



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 7/04</b>		A1	(11) International Publication Number: <b>WO 98/26716</b>
			(43) International Publication Date: 25 June 1998 (25.06.98)
<p>(21) International Application Number: PCT/US97/21917</p> <p>(22) International Filing Date: 2 December 1997 (02.12.97)</p> <p>(30) Priority Data: 08/769,156 18 December 1996 (18.12.96) US</p> <p>(71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410 Lightening View, Columbia, MD 21045 (US).</p> <p>(74) Agent: ROBERTS, Jon, L.; Roberts &amp; Brownell, L.L.C., Suite 212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>	
<p>(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT</p> <p>(57) Abstract</p> <p>An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low-loss acoustic transmission between the skin of the patient and the sensor assembly (102).</p>			

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**TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT****FIELD OF THE INVENTION**

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

**BACKGROUND OF THE INVENTION**

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable

1 alternative method of monitoring blood pressure. This is extremely important in trauma  
2 patients where prompt detection of blood pressure changes are needed to counteract the  
3 effects of shock or large blood loss.

4 The pulmonic circuit provides for blood circulation from the right ventricle through  
5 the pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and  
6 posteriorly from the heart, dividing into right and left branches which serve the right and left  
7 lungs, respectively. Within the lungs the right and left branches of the pulmonary artery  
8 divide repeatedly giving rise to arterioles that continue into the capillary networks associated  
9 with the walls of the alveoli. Gas exchange occurs as the blood moves through these  
10 capillaries, so that when the blood enters the venules of the pulmonary circuit, it is well  
11 oxygenated and poor in carbon dioxide. The pulmonary venules merge forming small veins,  
12 which in turn converge forming larger veins. Four pulmonary veins return oxygenated blood  
13 to the left atrium, thereby completing the pulmonic circuit.

14 None of the arteries of the pulmonic system are located in extremities and therefore  
15 measurement of pulmonic system pressure with a blood pressure cuff is not possible.

16 At present, the only reliable method for measuring pulmonic system blood pressure is  
17 through use of an invasive blood pressure catheter that is inserted directly into the pulmonary  
18 artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is  
19 thus generally seen as an unjustified procedure in patients without other symptoms.

20 The physician may attempt to detect and differentiate the abnormal sounds that occur  
21 with elevated blood pressure using traditional auscultation. Closure of the aortic and  
22 pulmonary semilunar heart valves generate a sound component that is in the audio frequency  
23 range. As the systemic or pulmonic blood pressure increases, the frequency components of  
24 the related heart valve also increase. This increased frequency audio component is not  
25 present in a healthy patient. However, aural detection of this frequency increase is extremely  
26 difficult because the physician must determine the absolute frequency of the audio component  
27 of the heart valve of interest. Additionally, the sounds are very weak and heavily  
28 contaminated with noise from other patient heart sounds, other normal patient body sounds  
29 and external ambient noise in the room. Further, the audio component of the aortic and  
30 pulmonary semilunar heart valves are heavily attenuated as they pass through the patient's  
31 chest and chest wall.

A need exists for a non-invasive, low cost and reliable means for determining systemic blood pressure in those situations where traditional means are contraindicated. A need also exists for a non-invasive, low cost and reliable means for determining pulmonary blood pressure.

## DESCRIPTION OF RELATED ART

As mentioned, the sounds related to systemic and pulmonary heart pressure are difficult to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent No. 3,790,712 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose relatively simple electronic stethoscopes as methods for amplification of the sounds in an attempt to raise the sub-audible components into the audible range. However, simple amplification of the entire frequency spectrum, as disclosed, does not help in determining the absolute frequency of the heart valve sounds, or in detecting the subtle changes of this frequency that occur with changes in blood pressure.

To this end, United States Patent No. 4,594,731 to Lewkowicz and United States Patent No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal processing on the audio signal in the electronic stethoscope. Lewkowicz discloses a means for shifting the entire detected spectrum of sounds upward while expanding the bandwidth so that they are more easily perceived by the listener. Dieken et al. discloses an electronic stethoscope having a greater volume of acoustic space and thereby improving low frequency response.

The electronic stethoscope provides a moderate improvement over conventional methods of auscultation. However, information remains in audio form only and is transient; the physician is unable to visualize the data and either freeze the display or focus on a particular element of the signal retrieved. To accommodate that deficiency, the technique of phonocardiography, which is the mechanical or electronic registration of heart sounds with graphic display, is used. United States Patent No. 5,218,969 to Bredesen et al.; United States Patent No. 5,213,108 to Bredesen et al.; United States Patent No. 5,012,815 to Bennett, Jr. et al.; United States Patent No. 4,967,760 to Bennett, Jr. et al.; United States Patent No. 4,991,581 to Andries; and United States Patent No. 4,679,570 to Lund et al. disclose

1 phonocardiography with signal processing and visual/audio output. United States Patent No.  
2 5,301,679 to Taylor; and United States Patent No. 4,792,145 to Eisenberg et al. disclose  
3 phonocardiography with signal processing and visual display.

4 The process of phonocardiography as commonly known in the art, acquires acoustic  
5 data through an air conduction microphone strapped to a patients chest, and provides the  
6 physician with a strip chart recording of this acoustic data. The strip chart is generally created  
7 at a rate of 100 mm/second. As this method is generally used, with the exception of the  
8 created strip chart, data is not stored. Thus, it is not possible to manipulate and/or process the  
9 data post acquisition. In addition, phonocardiography does not provide the sensitivity needed  
10 to monitor softer physiological sounds such as the closure of the semilunar valves and blood  
11 flow through the circulatory system.

12 As previously noted, one problem in traditional auscultation is ambient noise from the  
13 room in which the examination is occurring, which reduces the signal-to-noise ratio of the  
14 sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for  
15 automatic lung sound cancellation and provides visual and audio output. United States Patent  
16 No. 5,309,922 to Schechter et al. discloses a method for cancellation of ambient noise to  
17 enhance respiratory sounds and provides visual and audio output. United States Patent No.  
18 5,492,129 to Greenberger discloses a method for reducing general ambient noise and provides  
19 audio output.

20 United States Patent No. 5,036,857 to Semmlow et al. discloses a method of  
21 phonocardiography with piezoelectric transducer. Semmlow specifically recommends against  
22 Fast Fourier Transformation analysis of the phonocardiography data and relies on processing  
23 by other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States  
24 Patent No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

25 United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory  
26 sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the  
27 sensors are not physically attached to the patient. Thus the sensors are not capable of  
28 detecting the low intensity sound of the aortic and pulmonary semilunar heart valves.

29 Devices currently known in the art do not provide either a means of determining  
30 systemic blood pressure where use of a blood pressure cuff is contraindicated, or a low risk,  
31 non-invasive means of determining pulmonic blood pressure. Additionally, the related art

does not provide the level of aural sensitivity needed to reliably detect the sounds of the aortic and pulmonary semilunar heart valves and determine the precise frequency of these sounds.

What is needed is a safe, sensitive and noninvasive means of measuring systemic and/or pulmonic blood pressure. This is accomplished through the present invention. Through the use of sonospectrography, a procedure based on integral spectral analysis techniques, systemic pressure can be monitored in conditions where traditional auscultation is contraindicated. Additionally, sonospectrography can be used to monitor pulmonic pressure in an inexpensive, noninvasive and low risk manner, allowing for the early detection of conditions such as cystic fibrosis, pleuresy, lung pulmonary diseases and pulmonary impedance. Sonospectrography is defined as the separation and arrangement of the frequency components of acoustic signals in terms of energy or time.

Further embodiments of the present invention provide a means of detecting physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system. Analysis of these sounds can be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular blood clotting and carotid artery disease.

## SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide an apparatus, operation and method for the detection and analysis of physiological sounds, such as sounds emitted by the heart and other body organs as well as sounds related to the flow of blood through the circulatory system.

It is a further object of the present invention to provide an apparatus, operation and method to be used to determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery

1 disease.

2 It is a further object of the present invention to provide this apparatus, operation and  
3 method through the use of sonospectrography.

4 It is a further object of the present invention to provide this apparatus, operation and  
5 method through a synchronized and coordinated combination of sonospectrography and  
6 electrocardiogram signals.

7 It is a further object of the present invention to provide this apparatus, operation and  
8 method through visual display means that provide insight to the subtle characteristics of the  
9 acoustic signature.

10 It is a further object of the present invention to provide this apparatus, operation and  
11 method through selective time and frequency windowing of the acoustic signals.

12 It is a further object of the present invention to provide this apparatus, operation and  
13 method through real-time signal processing or recorded-signal post processing.

14 It is a further object of the present invention to provide this apparatus, operation and  
15 method through use of single or multiple transducers.

16 It is a further object of the present invention to provide this apparatus, operation and  
17 method through a computer assisted search algorithm to identify optimal placement of the  
18 transducer(s) on the patient's chest wall.

19 It is a further object of the present invention to provide this apparatus, operation and  
20 method in office environments with moderate to high ambient noise levels, through adaptive  
21 noise cancellation techniques.

22 It is a further object of the present invention to provide this apparatus, operation and  
23 method in a form that provides for dynamic template building to facilitate disease detection  
24 and identification.

25 It is a further object of the present invention to provide this apparatus, operation and  
26 method through neural network techniques.

27 It is a further object of the present invention to provide an acoustic coupling that  
28 minimizes signal loss between the subject-detector interface and allows for the detection of  
29 sounds heretofore undetectable in a normal room environment.

30 It is a further object of the present invention to extend the ability of clinicians to  
31 analyze sounds which are lower in amplitude than those detectable by the unaided ear.

1        It is a further object of the present invention to extend the ability of clinicians to  
2        analyze sounds which are lower in frequency than those detectable by typical auscultation  
3        techniques.

4        It is a further object of the present invention to increase detection of a specified  
5        frequency range through the use of a tailored bandpass amplifier.

6        It is a further object of the present invention to provide a means for data storage, data  
7        manipulation and data transmission.

8        It is a further object of the present invention to provide this apparatus, operation and  
9        method through advanced processing of acoustic signatures in the time and frequency domain  
10      to isolate and display the sound components associated with pulmonary and/or aortic heart  
11      valve closure.

12      It is a further object of the present invention to provide an apparatus, operation and  
13      method that is suitable for routine physical examination screening and early diagnosis of  
14      elevated pulmonic blood pressure thereby providing an opportunity for early intervention to  
15      enhance the patient's productive life.

16      It is a further object of the present invention to provide an apparatus, operation and  
17      method that is suitable for monitoring of systemic blood pressure in patients where use of a  
18      traditional blood pressure cuff is contraindicated.

19      These and other objects of the present invention will become obvious to those skilled  
20      in the art upon review of the following disclosure.

21      An apparatus for determining blood pressure in accordance with the present invention  
22      includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a  
23      mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The  
24      sensor assembly is connected to a data acquisition module which in turn is connected to a  
25      signal processing means. The signal processing means is connected to an electronic storage  
26      means, a hard copy reproduction means, a remote connection means and a monitor. In an  
27      alternative embodiment of the invention a plurality of sensor assemblies are connected to the  
28      data acquisition module. In another alternative embodiment of the invention a means for  
29      determining an electrocardiogram is connected to the signal processing means. In yet another  
30      alternative embodiment of the invention, data acquisition module is connected to high-fidelity  
31      earphones.

1                   The operation for determining blood pressure in accordance with the present invention  
2   includes:

- 3                   1)    performing start-up procedures;
- 4                   2)    acquiring physiologic signals;
- 5                   3)    acquiring ambient or background signals;
- 6                   4)    processing and subtracting ambient signals from physiologic signals;
- 7                   5)    conditioning and processing resultant data;
- 8                   6)    subjecting the conditioned and processed data to Fast Fourier Transformation;
- 9                   7)    passing the time domain components of the data through a time domain  
10                  correlator                   and feature extraction process;
- 11                  8)    passing the frequency domain components of the data through a frequency  
12                  domain                   correlator and feature extraction process;
- 13                  9)    comparing the time domain output and the frequency domain output to a  
14                  reference                   pattern and feature library;
- 15                  10)   determining whether the time domain output and frequency domain output  
16                  match                   known disease modalities;
- 17                  11)   determining whether a disease modality is indicated;
- 18                  12)   updating the reference pattern and feature library; and
- 19                  13)   providing the information regarding the disease modality to the physician so  
20                  that a  
21                    treatment regimen may commence.

22                  The method for determining blood pressure in accordance with the present invention  
23   includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where  
24   one wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is  
25   done by placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at  
26   the traditional auscultation point for the aortic valve. Where one wishes to monitor  
27   pulmonary pressure, the pulmonary semilunar valve is monitored. This is done by placing the  
28   acoustic coupling of the sensor assembly in contact with the patient's skin at the traditional  
29   auscultation point for the pulmonic valve. Detected signals are manipulated in the same  
30   fashion noted in the "operation" of the present invention. The signals may be viewed and  
31   analyzed by medical personnel at any number of points during this data manipulation process

1 to allow for the implementation of a treatment regimen. Where the sound emitted by either  
2 semilunar valve is of a higher than normal frequency, this is indicative of increased blood  
3 pressure in the corresponding circuit; that is, an increased frequency emitted by the aortic  
4 semilunar valve is indicative of higher than normal systemic blood pressure, while an  
5 increased frequency being emitted by the pulmonary semilunar valve is indicative of higher  
6 than normal pulmonary blood pressure.

7

8 BRIEF DESCRIPTION OF THE DRAWINGS

9

10 Figure 1 is a schematic representation of the overall architecture and user interface of  
11 the present invention.

12 Figure 2a depicts an exploded, oblique view of the sensor assembly.

13 Figure 2b depicts an exploded, side view of the sensor assembly.

14 Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor  
15 assembly.

16 Figure 4 depicts a circuit diagram of the electronic module, data cable and data  
17 acquisition module.

18 Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module,  
19 data cable and data acquisition module.

20 Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic  
21 module, data cable and data acquisition module.

22 Figure 7 depicts the frequency response of a tailored bandpass amplifier.

23 Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

24 Figure 9a illustrates an acoustic amplitude vs. time display mode.

25 Figure 9b illustrates a relative amplitude vs. frequency display mode.

26 Figure 9c illustrates a frequency vs. time display mode.

27 Figure 10 is a flow chart illustrating the operation of the present invention.

28 Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.

29

30 DETAILED DESCRIPTION

31

The present invention provides an apparatus, operation and method to passively and non-invasively measure systemic and pulmonic blood pressure through detection, identification and characterization of the acoustic signature associated with heart valve closure.

## APPARATUS

Referring to Figure 1, the overall architecture of the present invention is described. Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by sensor assembly 102. In an alternative embodiment a plurality of sensor assemblies can be used to either simultaneously obtain signals from various locations of the body or to simultaneously obtain signals from both the patient and the environment. Sensor assembly 102 is connected to data acquisition means 103.

Data acquisition means 103 comprises preamplifier 114, audio amplifier 116, and analog-to-digital converter 118. Preamplifier 114 electronically isolates the transducer, detects the electronic signals, and sends them to audio amplifier 116 and to analog-to-digital converter 118. Audio amplifier 116 drives one or more sets of high-fidelity earphones 120. Analog-to-digital converter 118 samples the analog signal and converts it to a binary number for each time sample. Data acquisition means 103 is connected to signal processing means 104.

Signal processing means 104 is a general-purpose microprocessor. Signal processing means 104, also has means for video display of information, such as monitor 112. Signal processing means 104 is connected to electronic data storage means 106, operator input means 107, hard copy reproduction means 108 and remote connection means 110.

Various types of electronic data storage are known to those skilled in the art. In alternative embodiments electronic data storage means 106 comprises: internal hard disk drive, external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM. Likewise, various types of operator input means are known to those skilled in the art. In alternative embodiments operator input means 107 comprises: keyboard, mouse, voice detector or other means. Hard copy reproduction means 108 provides copies of images displayed on monitor 112 for purposes such as maintaining medical records, assisting

1 consultations, and assisting data processing and review. Remote connection means **110** is a  
2 modem. In alternative embodiments, the system of the present invention may be directly  
3 linked to a network via a network interface card or other suitable means. Thus a modem may  
4 not always be necessary.

5 In an alternative sensor assembly embodiment, sensor assembly **102** can detect both  
6 physiologic and background signals. In another alternative sensor assembly embodiment, one  
7 side of sensor assembly **102** comprises an audio transducer which is in contact with the skin  
8 while a second audio transducer on the opposite side faces away from the patient. This  
9 second transducer is designed to acquire ambient sounds in synchronism with the sounds  
10 reaching the transducer in contact with the patient's skin to reject common mode signals  
11 reaching both transducers. By adding the environmental signals out of phase with the signals  
12 acquired from the patient, the sounds in common to both transducers are effectively canceled.  
13 In yet another alternative sensor assembly embodiment the target frequency range for data  
14 acquisition is about 200 to 2000 Hz. In another alternative sensor assembly embodiment, the  
15 target frequency range for signal acquisition is about 400 hertz.

16 In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise  
17 data acquisition and proper impedance matching.

18 In an alternative analog-to-digital converter embodiment analog-to-digital converter  
19 **118** has a sample rate about 4 to 48 Khz. In yet another alternative analog-to-digital converter  
20 embodiment, analog-to-digital converter **118** has a sample rate of about 44 Khz. In another  
21 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a  
22 resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment,  
23 analog-to-digital converter **118** has a linearity about  $\pm 0.005$  percent of full scale. In another  
24 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a  
25 sample length of about one to sixty seconds. In yet another alternative analog-to-digital  
26 converter embodiment, analog-to-digital converter **118** has an operator selectable sample  
27 length.

28 In an alternative earphones embodiment, earphones **120** have separate volume  
29 controls.

30 In an alternative signal processing means embodiment, signal processing means **104** is  
31 a computer with a central processing unit. In another alternative signal processing means

1 embodiment, signal processing means **104** is an IBM compatible personal computer using an  
2 INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a  
3 minimum hard disk size of 500 MB. In yet another alternative signal processing means  
4 embodiment, signal processing means **104** is a Macintosh PowerPC.

5 In an alternative monitor embodiment, monitor **112** has a minimum display size of  
6 600 X 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another  
7 alternative monitor embodiment, monitor **112** is a high resolution EGA or VGA color display  
8 monitor.

9 In an alternative signal processing means embodiment, signal processing means **104**  
10 comprises a sound card. In another alternative signal processing means embodiment, the  
11 sound card comprises a "Tahiti" multiple channel computer sound card manufactured by  
12 Turtle Beach, although sound cards such as the Pro Audio 1b (Media Vision) can also be  
13 used.

14 In an alternative hard copy reproduction means embodiment, hard copy reproduction  
15 means **108**, is a printer. In another alternative hard copy reproduction means embodiment,  
16 hard copy reproduction means **108** is a printer capable of generating a variety of different  
17 graphic displays. In yet another alternative hard copy reproduction means embodiment, hard  
18 copy reproduction means **108** is a laser printer.

19 In an alternative remote connection means embodiment, remote connection means  
20 **110** is an internal or external, high speed modem. In another alternative remote connection  
21 means embodiment, remote connection means **110** has a speed of at least 14.4 kilobytes per  
22 second.

23 Referring to Figure 2a, an oblique view of an embodiment of sensor assembly **102** is  
24 shown. Figure 2b depicts a side view of an embodiment of sensor assembly **102**. Housing  
25 **302** comprises a sound deadening material having sufficient mass to dampen high frequency  
26 ambient disturbances and hold the sensor assembly in contact with the patient through  
27 gravity. Housing **302** has housing front **304** and housing back **306**. Rim **308** is located on the  
28 periphery of housing front **304**. First indentation **310** runs parallel and adjacent to the inside  
29 of rim **308**. Second indentation **312** runs parallel and adjacent to the inside of first  
30 indentation **310**. Bore **312** is approximately centrally located within second indentation **312**  
31 and is shaped and sized in conformity to the shape and size of electronic module **314**.

1      Electronic module **314** nests within bore **312** of housing **302**. As will be further discussed,  
2      signal detection and processing circuitry are incorporated within electronic module **314**.

3           Shock dampener **316** is positioned adjacent to first indentation **310**. Mounting means  
4      **318** is positioned adjacent to shock dampener **316**. Transducer **320** is positioned within  
5      mounting means **318**. Transducer **320** converts detected signals into electronic signals.  
6           Acoustic coupling **322** is positioned adjacent to transducer **320**. Acoustic coupling **322**  
7      serves to dilinearize excitation response and reduce dynamic range.

8           Once assembled, housing **302** is closed to the ambient environment with back cover  
9      **324**. Sensor assembly **102** comprising all the individual sensor elements, is assembled and  
10     sealed to form a single complete unit.

11          In an alternative housing embodiment, housing **302** is composed of nickel plated  
12     aluminum, but can be any material having sufficient mass to dampen high frequency ambient  
13     disturbances and hold the sensor in contact with the patient through gravity.

14          In an alternative sensor assembly embodiment, when electronic module **314** nests  
15     within bore **312** of housing **302**, top **316** of electronic module **314** is flush with second  
16     indentation **312**.

17          In an alternative shock dampener embodiment shock dampener **316** is an "O" ring.

18          In an alternative mounting means embodiment, mounting means **318** is a plastic  
19     mounting ring.

20          In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In  
21     another alternative transducer embodiment, transducer **320** has a high impedance. In yet  
22     another alternative transducer embodiment, transducer **320** has an impedance of about 470  
23     Kohms. In another alternative transducer embodiment, transducer **320** has high efficiency as  
24     compared with conventional electromagnet type speakers. In yet another alternative  
25     transducer embodiment, transducer **320** is ultra thin and lightweight. In another alternative  
26     transducer embodiment, transducer **320** has a frequency range of about 500 - 20,000 Hz. In  
27     yet another alternative transducer embodiment, transducer **320** has a capacitance at 120 Hz of  
28     about  $60 \pm 30\%$  nF. In another alternative transducer embodiment, transducer **320** current  
29     leakage is limited to about one micro ampere.

30          In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance  
31     matched, and serves to provide a low-loss acoustic transmission coupling between the skin of

1 the patient and transducer 320, thereby minimizing signal loss across the subject-detector  
2 interface. In another alternative acoustic coupling embodiment, acoustic coupling 322 is a  
3 parametric acoustic transconductor. In yet another acoustic coupling embodiment, acoustic  
4 coupling 322 has a high conduction coefficient. In another alternative acoustic coupling  
5 embodiment, acoustic coupling 322 is made of latex foam. In yet another alternative acoustic  
6 coupling embodiment, acoustic coupling 322 is logarithmically attenuated, having low  
7 transmission at low frequencies and high transmission at high frequencies.

8 Referring to Figure 3 an oblique exploded view of an alternative embodiment of  
9 sensor assembly 102 is shown. Housing 402 comprises a sound deadening material having  
10 sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly  
11 in contact with the patient through gravity. Housing 402 has housing front 404 and housing  
12 back 406. First rim 408 is located on the periphery of housing front 404. Second rim 410 is  
13 located on the periphery of housing back 406. First indentation 412 runs parallel and adjacent  
14 to the inside of first rim 408. Second indentation 414 runs parallel and adjacent to the inside  
15 of first indentation 412. Third indentation 416 runs parallel and adjacent to the inside of  
16 second rim 410. Fourth indentation 418 runs parallel and adjacent to the inside of third  
17 indentation 416. First bore 420 is approximately centrally located within second indentation  
18 414 and is shaped and sized in conformity to the shape and size of first electronic module  
19 422. Second bore 440 is approximately centrally located within fourth indentation 418 and is  
20 shaped and sized in conformity to the shape and size of second electronic module 442. First  
21 electronic module 422 nests within first bore 420 of housing 402. Second electronic module  
22 442 nests within second bore 440 of housing 402. As will be further discussed, signal  
23 detection and processing circuitry are incorporated within first and second electronic module  
24 422, 442.

25 First shock dampener 424 is positioned adjacent to first indentation 412. Second  
26 shock dampener 426 is positioned adjacent to third indentation 416. First mounting means  
27 428 is positioned adjacent to first shock dampener 424. Second mounting means 430 is  
28 positioned adjacent to second shock dampener 426. First transducer 432 is positioned within  
29 first mounting means 428. Second transducer 434 is positioned within second mounting  
30 means 430. First transducer 432, converts detected physiologic signals into electronic  
31 signals. Second transducer 434, converts detected environmental or background signals into

1 electronic signals. First acoustic coupling 436 is positioned adjacent to first transducer 432.  
2 Second acoustic coupling 438 is positioned adjacent to second transducer 434. First and  
3 second acoustic coupling 436, 438 serve to dilinearize excitation response and reduce  
4 dynamic range.

5 In an alternative housing embodiment, housing 402 is composed of nickel plated  
6 aluminum.

7 In an alternative shock dampener embodiment, first and second shock dampener 424,  
8 426 is an "O" ring.

9 In an alternative mounting means embodiment, first and second mounting means 428,  
10 430 is a plastic mounting ring.

11 In an alternative transducer embodiment, first and second transducer 432, 434 is a  
12 piezoelectric disk. In another alternative transducer embodiment, first and second transducer  
13 432, 434 has a high impedance. In yet another alternative transducer embodiment, first and  
14 second transducer 432, 434 has an impedance of about 470 Kohms. In another alternative  
15 transducer embodiment, first and second transducer 434, 434 has high efficiency as compared  
16 with conventional electromagnet type speakers. In yet another alternative transducer  
17 embodiment, first and second transducer 432, 434 is ultra thin and lightweight. In another  
18 alternative transducer embodiment, first and second transducer 432, 434 has a frequency  
19 range of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and  
20 second transducer 432, 434 has a capacitance at 120 Hz of about  $60 \pm 30$  % nF. In another  
21 alternative transducer embodiment, first and second transducer 432, 434 current leakage is  
22 limited to about one micro ampere.

23 In an alternative acoustic coupling embodiment, first and second acoustic coupling  
24 436, 438, is impedance matched, and serves to provide a low-loss acoustic transmission  
25 coupling between the skin of the patient and first transducer 432, thereby minimizing signal  
26 loss across the subject-detector interface. In another alternative acoustic coupling  
27 embodiment, first and second acoustic coupling 436, 438 is a parametric acoustic  
28 transconductor. In yet another acoustic coupling embodiment, first and second acoustic  
29 coupling 436, 438 has a high conduction coefficient. In another alternative acoustic coupling  
30 embodiment, first and second acoustic coupling 436, 438 is made of latex foam. In yet  
31 another alternative acoustic coupling embodiment, acoustic coupling 322 is logarithmically

1 attenuated, having low transmission at low frequencies and high transmission at high  
2 frequencies.

3 Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data  
4 acquisition module **504** of the present invention are shown in schematic form. In  
5 combination, first resistor **506**, semiconductor device **508**, second resistor **510**, and first  
6 capacitor **512** comprise electronic module **314**. Electronic module **314** performs functions  
7 such as signal amplification, and filtering. Transducer **320** is connected in parallel with first  
8 resistor **506**, second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor  
9 **508** serves to modulate current. First capacitor **512** provides gain and source decoupling for  
10 semiconductor **508**.

11 In an alternative first resistor embodiment, first resistor **506** provides a matching load  
12 to transducer **320**. In another alternative first resistor embodiment first resistor **506** has a  
13 resistance of 470 Kohms.

14 In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

15 In an alternative semiconductor embodiment, semiconductor **508** is field effect  
16 transistor. In another alternative semiconductor embodiment, semiconductor **508** is a field  
17 effect transistor with an N-type base.

18 In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and  
19 is connected to ground.

20 Figure 5 depicts a circuit diagram of the electronic module, data cable and data  
21 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer  
22 **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic  
23 module **314** to data acquisition module **504**. Data acquisition module **504** comprises an  
24 amplifier. As depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having  
25 a DC injection point. The amount of DC injection is made variable by value selection of  
26 variable resistor **610**. In an alternative value selection embodiment, value selection is  
27 determined by the practitioner. In yet another alternative value selection embodiment, value  
28 selection is determined automatically by the signal processing means in conformity with  
29 predetermined parameters.

30 In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein  
31 two insulated wires are twisted forming a flexible line without the use of spacers. In another

1 alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel  
2 conductors are separated from each other and surrounded by a solid dielectric. In this  
3 alternative embodiment, the conductors are contained within a copper-braid tubing that acts  
4 as a shield. The assembly is covered with a rubber or flexible composition coating to protect  
5 the line against moisture and friction. There are two advantages of this alternative  
6 embodiment: (1) the capacitance between each conductor and ground is uniform along the  
7 entire length of the line; and (2) the wires are shielded against pickup of stray electric fields.  
8 In yet another alternative embodiment shielded pair **604** data cable **502** is connected to sensor  
9 housing **610** and to ground as a means for reducing electrical noise and increasing patient  
10 safety.

11 In an alternative data acquisition module embodiment, data acquisition module **504**  
12 has a low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a  
13 level 20 dB higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In  
14 another alternative data acquisition module embodiment, data acquisition module **504**  
15 comprises a voltage gain, variable from zero to fifty, allowing recovery of low-level sounds  
16 from 600 to about 2000 Hz while preserving the ability to measure low-frequency signals  
17 having a relatively high amplitude, without amplifier saturation.

18 In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7,  
19 and lowpass filter **608** drives an output amplifier with a gain of about 7. In another  
20 alternative highpass filter embodiment the overall voltage gain available with the gain  
21 potentiometer at maximum will be about 50. An advantage of this alternative embodiment is  
22 the ability to reject a narrow range of frequencies in a notch caused by the phase delay in the  
23 components of highpass filter **606**. In an alternative highpass filter embodiment this notch is  
24 set at 100 Hz. In another alternative highpass filter embodiment this notch is set at about 50 -  
25 60 Hz, thereby providing a measure of hum rejection

26 Figure 6 depicts a circuit diagram of the electronic module, data cable and data  
27 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer  
28 **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network  
29 **702** gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz  
30 that is related to the combined resistor/capacitor time constants of the network. Field effect  
31 transistor **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-

1 type operational amplifier pair.

2 Figure 7 depicts an idealized shape of an amplifier having low-frequency response  
3 from first point **802** to crossover point **804** and having higher frequency response of  
4 predetermined level **806**, from second point **808** to third point **810**. In an alternative  
5 embodiment, first point **802** is about 10 Hz, crossover point **804** is about 100 Hz,  
6 predetermined level **806** is about 20 dB, second point **808** is about 600 Hz and third point **810**  
7 is about 2 KHz. In yet another alternative embodiment, crossover point **804** is about 60 Hz.

8 Figure 8 further depicts the response of the tailored bandpass amplifier, plotting  
9 amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In  
10 alternative embodiments, the response of sounds of interest **908** may be set at varying levels  
11 **910**.

12 Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography  
13 data. In the simultaneous display mode, the present invention provides for plotting  
14 electrocardiogram data and sonospectrography data as a function of intensity **1002** and time  
15 **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that  
16 may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be  
17 visually correlated with a select part of the acoustic signal **1010** and differentially measured to  
18 within 23 millionths of a second. This allows an operator who may be less familiar with  
19 acoustic signatures to correlate the electrocardiogram signal, which may be well understood,  
20 with the acoustic signal.

21 Referring to Figures 10a, 10b, and 10c, the display methodology of the present  
22 invention is shown. The present invention provides a means to simultaneously display the  
23 signal of interest in a variety of different forms. In Figure 10a, the signal of interest of the  
24 present invention is presented as a simple time series, with acoustic amplitude **1102** on the  
25 vertical scale and time **1104** on the horizontal scale. In Figure 10b, the signal of interest of the  
26 present invention is presented as a time and frequency display, with relative amplitude  
27 **1106** of each slice of the frequency spectrum on the vertical scale and frequency spectrum  
28 **1108** on the horizontal display. In Figure 10c, the signal of interest of the present invention is  
29 presented with frequency **1110** on the vertical axis, time **1112** on the horizontal axis, and  
30 relative amplitude plotted in different color hues (not shown) and/or grey scale intensity.

31 Having thus described the basic concept of the apparatus of the invention, it will be

1 readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to  
2 be presented by way of example only, and is not limiting. Various alterations, improvements  
3 and modifications will occur and are intended to those skilled in the art, but are not expressly  
4 stated herein. For example, while cardiovascular monitoring is a key aspect of the invention,  
5 the techniques described herein are equally applicable to the monitoring of other body organs  
6 and regions of the body of both humans and animals and thus may also find utility in the  
7 veterinary sciences. These modifications, alterations and improvements are intended to be  
8 suggested hereby, and are within the spirit and scope of the invention.

9

10 **OPERATION**

11

12 Figure 11 depicts the operation of the apparatus of the present invention with  
13 associated hardware and software. At step **1202**, start-up procedures are performed such as  
14 initialization, calibration, sensor selection, patient parameter input, and buffer clearing,  
15 among others. Upon completion of these start-up procedures steps **1204** and **1206** are  
16 initiated. At step **1204**, sensor **102** provides patient physiologic signals for signal processing.  
17 In an alternative embodiment, sensor **102** can include electrocardiogram sensors and acoustic  
18 sensors. At step **1206** acoustic sensors are used to detect background or ambient noise.

19 Next, at step **1208**, the detected signals are passed to individual data acquisition  
20 modules which contain means for signal filtering, impedance matching, amplification, and  
21 buffering. These functions are performed by the components of the circuitry illustrated in  
22 Figs. 4-6.

23 At step **1210**, the signals from the ambient noise acoustic sensor acquired in step  
24 **1206**, are processed and subtracted from the signals from the desired sensor of step **1204** in a  
25 noise cancellation process to reduce the effect of ambient noise from the patient's  
26 environment.

27 At step **1212**, the signal undergoes additional signal conditioning and processing. The  
28 purpose of this conditioning step is to convert the analog signal to digital, provide adjustable  
29 decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing,  
30 averaging and peak holding. In an alternative embodiment the signal conditioning and  
31 processing of step **1212** is performed by a sound card which typically has the following

1 capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16  
2 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion;  
3 and (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet  
4 another alternative embodiment the sound card used comprises a "Tahiti" multiple channel  
5 Sound Card manufactured by Turtle Beach. Step **1230** allows for the intermediate output and  
6 display of the desired signal following the signal conditioning and processing of step **1212**.  
7 The display is accomplished by selection of a desired display mode and subsequent display on  
8 the monitor **112**. The output of step **1212** is of a time series and is suitable for display  
9 selection as in Figure 10a.

10 At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier  
11 transformation. The output of step **1214** is of time and frequency and is suitable for display  
12 selection according to Figures 10b or 10c.

13 At step **1216**, time domain components of the data passes through a time domain  
14 correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency  
15 domain components of the data passes through a frequency domain correlator and feature  
16 extractor. In step **1220**, the outputs from the time domain correlator and feature extraction  
17 process of step **1216** and the frequency domain correlator and feature extractor of step **1218**  
18 are compared to a reference pattern and feature library, to determine whether the features  
19 contained within the signal of interest match known disease modalities as recorded and  
20 maintained within the reference pattern and feature library.

21 At step **1222**, the outputs from the time domain correlator and feature extraction  
22 process of step **1216**, the frequency domain correlator and feature extractor process of step  
23 **1218** and the results from the reference pattern and feature library comparison of step **1220**  
24 are subjected to a recognition logic decision, where a determination is made as to whether a  
25 disease or adverse condition is indicated. At step **1224**, the new disease modality indicated in  
26 the recognition logic decision of step **1222** is then used to update the reference pattern and  
27 feature library of step **1220**. In step **1226** a desired display mode such as depicted in Figures  
28 10a, 10b and 10c is chosen for subsequent display on the monitor **112**. At step **1228** the  
29 process is either terminated at step **1240** or begun anew at step **1202**.

30 The preceding descriptions of the operation of the present invention are merely  
31 illustrative. In various embodiments of the disclosed invention operational steps may be

1 added, eliminated, performed in parallel or performed in a differing order.

2

3

### METHOD

4

5 Sonospectrography can be used as a primary source of auscultatory information in a  
6 routine physical examination or in population screening. Sonospectrography can be used in  
7 cardiology and general medicine for the detection of functional and organic disorders of the  
8 heart such as congenital defects, valve function, diseases of the pericardium and myocardium  
9 and systemic and pulmonary hypertension. Sonospectrography can also be used as a  
10 traditional stethoscope to capture sounds generated by other organs, such as the lungs,  
11 trachea, larynx, liver and carotid arteries.

12

13 Elevated blood pressure has a number of causes. Regardless of the cause, however,  
14 recent testing at the Uniformed Services University of Health Sciences shows that there is a  
15 change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds  
16 that is directly correlated to change in blood pressure of the associated systemic or pulmonary  
17 circulatory system. This correlation was shown to be both measurable and repeatable in  
18 testing on animals having systemic and pulmonary circulatory systems comparable to the  
human system.

19

20 Elevated blood pressure increases back pressure at associated heart valves. This  
21 increased back pressure results in more rapid closure of the heart valves and a resultant  
22 audible "snap" of the valve leaflets. The acoustic signature that is associated with those heart  
23 valve sounds has elevated frequency components as compared to the signature associated  
24 with heart valves operating under normal blood pressures. As the blood pressure increases,  
25 this frequency component also increases. It has been determined that this change in the  
26 frequency component is transitory and returns to normal when the blood pressure returns to  
normal.

27

28 Thus, where the sound emitted by the aortic semilunar valve is of an increased  
29 frequency, this is indicative of higher systemic blood pressure. Similarly, where the sound  
30 emitted by the pulmonary semilunar valve is of an increased frequency, this is indicative of  
higher pulmonic blood pressure. Through the use of the apparatus of the present invention, it  
31 is possible to detect and record sounds originating from the aortic and pulmonary semilunar

1        valves.

2        In practice, a sensor assembly is placed in contact with the patient. One side of the  
3        sensor assembly contains an acoustic coupler that is placed in contact with the patient's skin  
4        at the traditional auscultation point for the valve of interest, while a second acoustic coupler  
5        on the opposite side faces away from the patient. This second acoustic coupler is designed to  
6        acquire background sounds in synchronism with the acoustic coupler in contact with the  
7        patient's skin to reject common mode signals reaching both couplers. While breathing  
8        normally the sounds of the aortic and/or pulmonary semilunar valves are acquired,  
9        preamplified and sent to a plurality of locations.

10       One analog signal is sent directly to an audio amplifier and high fidelity earphones. A  
11       second analog signal is sent through a gain control potentiometer to an analog to digital  
12       converter. The data is digitized and displayed in real time on a monitor. Visual feedback  
13       from the monitor allows a precise setting of the gain control by the physician for the optimum  
14       acquisition of data. In an alternative embodiment, an electronic strip chart is used in the  
15       precise setting of the gain control. The physician adjusts gain control to maximize the  
16       dynamic range of the captured signal.

17       In one embodiment, sounds are filtered normally. In an alternative embodiment,  
18       sounds are filtered to de-emphasize interfering responses prior to being sent to the earphones  
19       or the analog to digital converter. Data can be stored digitally, recalled for future analysis or  
20       transmitted to another location.

21       Referring to Figure 12, data from recent in-vivo testing on animal subjects at the  
22       Uniformed Services University of Health Sciences is shown. The subject had a pressure  
23       catheter emplaced to provide actual pressure readings, and the present invention detected, and  
24       processed the acoustic signature data from the second heart sounds. Figure 12 plots the  
25       relationship between second heart sound A2 1302, and blood pressure 1304. As shown,  
26       where there is a rise in the frequency of second heart sound 1302, there is a corresponding  
27       rise in systolic pressure 1306, mean pressure 1308 and diastolic pressure 1310.

28       The subject whose pressure/frequency relationship is depicted in Figure 12, had a  
29       resting systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg,  
30       and a predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was  
31       thus about 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased,

1 the associated frequency components of the second heart sound correspondingly increased.  
2 Systolic pressure 1306 of the subject reached about 165 mm Hg, diastolic pressure 1310  
3 reached about 85 mm Hg, and frequency of second heart sound 1302 reached 36. Mean  
4 pressure 1308 reached about 115 mm Hg. The slope of this mean pressure/frequency curve is  
5 approximately 2 mm Hg per Hz. This pressure/frequency correlation was demonstrated in  
6 each animal subject tested.

7 Across a population, measurement of the sound frequency associated with the closure  
8 of the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and  
9 pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected  
10 from population samples, the present invention will allow an estimate of the mean systemic  
11 and pulmonary pressure with a passive and non-invasive acoustic measurement of the  
12 acoustic signature of the semilunar valve closure. As an example, if the mean pressure data  
13 curve 1307 in Figure 12 presented an accumulated average from the population, then  
14 measurement of a pulmonary semilunar valve closure sound frequency of 36 Hz 1309 would  
15 provide an estimate that the mean pulmonic pressure was 115 mm Hg 1311. In an otherwise  
16 asymptomatic patient, this might provide sufficient clinical justification for use of an invasive  
17 blood pressure catheter, with the attendant risk and cost, to confirm the pulmonic pressure.

18 Although the method of the present invention has been described in detail for purpose  
19 of illustration, it is understood that such detail is solely for that purpose, and variations can be  
20 made therein by those skilled in the art without departing from the spirit and scope of the  
21 invention. The apparatus, operation and method of the present invention is defined by the  
22 following claims.

1       **WHAT IS CLAIMED IS:**

2

3       1. An apparatus for monitoring blood pressure comprising:

4       a means for detecting audio signals;

5       a means for signal processing connected to the signal detecting means;

6       a means for signal storage connected to the signal processing means; and

7       a means for monitoring, connected to the signal processing means.

8       2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the

9       audio signal detecting means is a sensor assembly.

10      3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the

11       audio signal detecting means is a plurality of sensor assemblies.

12      4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the

13       sensor assembly comprises:

14       a housing having a front and a back;

15       an electronic module connected to the housing;

16       a shock dampener connected to the front of the housing;

17       a means for mounting connected to the housing;

18       a transducer connected to the mounting means;

19       an acoustic coupling connected to the transducer; and

20       a cover connected to the back of the housing.

21      5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the

22       housing further comprises a sound deadening material.

23      6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the

24       housing further comprises nickel plated aluminum.

25      7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the

26       housing further comprises:

27       a rim having an inside and an outside, located on the periphery of the front of the

28       housing;

29       a first indentation having an inside and an outside, that runs parallel and adjacent to

30       the inside of the rim;

31       a second indentation that runs parallel and adjacent to the inside of the first

1 indentation; and

2 a bore that is approximately centrally located within the second indentation.

3 8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the  
4 electronic module nests within the bore.

5 9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
6 shock dampener is an "O" ring.

7 10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
8 mounting means is a plastic mounting ring.

9 11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
10 transducer is a piezoelement.

11 12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
12 acoustic coupling is a parametric acoustic transconductor.

13 13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein  
14 the parametric acoustic transconductor comprises latex foam.

15 14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
16 signal processing means is a computer with a central processing unit.

17 15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein  
18 the computer with a central processing unit is an IBM compatible personal computer.

19 16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
20 means for signal storage further comprises an array of disks.

21 17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
22 means for signal storage further comprises an internal hard disk drive.

23 18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
24 means for signal storage further comprises an internal hard disk drive.

25 19. An apparatus for monitoring blood pressure as claimed in claim 1, further  
26 comprising:

27 a means for hard copy reproduction connected to the signal processing means.

28 20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein  
29 the means for hard copy reproduction further comprises a printer.

30 21. An apparatus for monitoring blood pressure as claimed in claim 1, further  
31 comprising:

1 a means for remote connection connected to the signal processing means.

2 22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein  
3 the means for remote connection further comprises a modem.

4 23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
5 means for monitoring further comprises a high resolution EGA color display monitor.

6 24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
7 means for monitoring further comprises a high resolution VGA color display monitor.

8 25. An apparatus for monitoring blood pressure as claimed in claim 1, further  
9 comprising:

10 a means for data acquisition connected to the signal detection means and the signal  
11 processing means.

12 26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein  
13 the means for data acquisition comprises an amplifier.

14 27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein  
15 the amplifier comprises a tailored bandpass amplifier.

16 28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein  
17 the tailored bandpass amplifier comprises a low frequency response from a predetermined  
18 first point to a predetermined second point, and a higher frequency response of a  
19 predetermined level, from the predetermined second point to a predetermined third point.

20 29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein  
21 the predetermined level is about 20 dB.

22 30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein  
23 the predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz  
24 and the predetermined third point is about 600 Hz.

25 31. An apparatus for monitoring blood pressure as claimed in claim 28, where in  
26 the predetermined second point is about 60 Hz.

27 32. A method of determining blood pressure comprising:

28 performing initialization procedures;

29 acquiring physiologic signals;

30 acquiring background signals;

31 subtracting background signals from physiologic signals creating physiologic data;

1 processing physiologic data forming a time domain output and a frequency domain  
2 data output;

3 comparing the time domain output and the frequency domain output with a reference  
4 pattern and feature library; and

5 determining if a disease modality is indicated.

6 33. A method of determining blood pressure as claimed in claim 32, wherein  
7 performing initialization further comprises:

8 initializing system;

9 calibrating system;

10 selecting sensors;

11 inputting patient parameters; and

12 clearing buffers.

13 34. A method of determining blood pressure as claimed in claim 32, wherein  
14 acquiring physiologic signals comprises acquiring acoustic signals.

15 35. A method of determining blood pressure as claimed in claim 32, wherein  
16 acquiring physiologic signals comprises acquiring electric signals.

17 36. A method of determining blood pressure as claimed in claim 32, wherein the  
18 physiologic signals are in an analog form, further comprising:

19 converting, the physiologic signals from the analog form to a digital form.

20 37. A method of determining blood pressure as claimed in claim 32, wherein the  
21 background signals are in an analog form, further comprising the step:

22 converting the background signals from the analog form to a digital form.

23 38. A method of determining blood pressure as claimed in claim 32, wherein  
24 processing further comprises:

25 applying signal conditioning and time domain averaging to the physiologic data  
26 forming conditioned and averaged data;

27 formatting the conditioned and averaged data in an array creating formatted data;

28 aligning and normalizing formatted data, creating aligned and formalized data;

29 normalizing and integrating the aligned and formalized data, creating normalized and  
30 integrated data, wherein said normalized and integrated data has time domain components  
31 and frequency domain components;

1                   passing the time domain components of the normalized and integrated data through a  
2                   time domain correlator and feature extraction process; and

3                   passing the frequency domain components of the normalized and integrated data  
4                   through a frequency domain correlator and feature extractor, creating the time domain output  
5                   and the frequency domain output.

6                 39.    A method of determining blood pressure as claimed in claim 38, further  
7                   comprising:

8                   displaying the formatted data on a monitor.

9                 40.    A method of determining blood pressure as claimed in claim 38, further  
10                   comprising:

11                   displaying the aligned and normalized data on a monitor.

12                 41.    A method of determining blood pressure as claimed in claim 38, further  
13                   comprising:

14                   displaying the normalized and integrated data on a monitor.

15                 42.    A method of determining blood pressure as claimed in claim 32, further  
16                   comprising:

17                   updating the reference pattern and feature library.

18                 43.    A method of determining systemic blood pressure using sonospectrography  
19                   analysis comprising:

20                   monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein  
21                   the sound is detected using a sensor assembly, to monitor physiologic signals, the sensor  
22                   assembly comprising:

23                   a housing having a front and a back;

24                   an electronic module connected to the housing;

25                   a shock dampener connected to the front of the housing;

26                   a means for mounting connected to the housing;

27                   an acoustic coupler connected to the mounting means;

28                   a transducer connected to the acoustic coupler; and

29                   a cover connected to the back of the housing;

30                   processing the physiologic signals, the processing comprising:

31                   applying signal conditioning and time domain averaging to the physiologic

1                   signals to form conditioned and averaged data;  
2                   formatting the conditioned and averaged data in an array to create formatted  
3                   data;  
4                   aligning and normalizing formatted data, to create aligned and formalized data;  
5                   normalizing and integrating the aligned and formalized data, to create  
6                   normalized and integrated data that has time domain components and  
7                   frequency domain components;  
8                   passing the time domain components of the normalized and integrated data  
9                   through a time domain correlator and feature extraction process;  
10                  passing the frequency domain components of the normalized and integrated  
11                  data through a frequency domain correlator and feature extractor, to create a  
12                  time domain output and a frequency domain output;  
13                  comparing time domain output and the frequency domain output with a reference  
14                  pattern and feature library; and  
15                  determining if a disease modality is indicated.

16                  44. A method of determining systemic blood pressure using sonospectrography  
17                  analysis as claimed in claim 43, further comprising:

18                  acquiring background signals; and  
19                  subtracting background signals from physiologic signals.

20                  45. A sensor assembly for detecting physiological sounds comprising:  
21                  a housing having a front and a back;  
22                  an electronic module connected to the housing;  
23                  a shock dampener connected to the front of the housing;  
24                  a means for mounting connected to the shock dampener;  
25                  an acoustic coupler connected to the mounting means;  
26                  a transducer connected to the acoustic coupler; and  
27                  a cover connected to the back of the housing.

28                  46. A sensor assembly as claimed in claim 45, wherein the housing further  
29                  comprises a sound deadening material.

30                  47. A sensor assembly as claimed in claim 46, wherein the housing further  
31                  comprises nickel plated aluminum.

1           48.    A sensor assembly as claimed in claim 45, wherein the housing further  
2   comprises:

3           a rim having an inside and an outside, that is located on the periphery of the front of  
4   the housing;

5           a first indentation having an inside and an outside, that runs parallel and adjacent to  
6   the inside of the rim;

7           a second indentation that runs parallel and adjacent to the inside of the first  
8   indentation; and

9           a bore, that is approximately centrally located within the second indentation.

10          49.    A sensor assembly as claimed in claim 48, wherein the electronic module nests  
11   within the bore.

12          50.    A sensor assembly as claimed in claim 45, wherein the shock dampener is an  
13   “O” ring.

14          51.    A sensor assembly as claimed in claim 45, wherein the mounting means is a  
15   plastic mounting ring.

16          52.    A sensor assembly as claimed in claim 45, wherein the transducer is a  
17   piezoelement.

18          53.    A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a  
19   parametric acoustic transconductor.

20          54.    A sensor assembly as claimed in claim 53, wherein the parametric acoustic  
21   transconductor comprises latex foam.

22          55.    A sensor assembly for detecting physiological sounds comprising:  
23           a housing, having a front, a back, and an interior;  
24           an electronic module that nests in the interior of the housing;  
25           a first shock dampener connected to the front of the housing;  
26           a first mounting means connected to the first shock dampener;  
27           a transducer connected to the first mounting means;  
28           a first acoustic coupling connected to the transducer;  
29           a second shock dampener connected to the back of the housing;  
30           a second mounting means connected to the second shock dampener;  
31           a second transducer connected to the second mounting means; and

1 a second acoustic coupling connected to the second transducer.

2 56. A sensor assembly as claimed in claim 55, wherein the housing further  
3 comprises a sound deadening material.

4 57. A sensor assembly as claimed in claim 56, wherein the housing further  
5 comprises nickel plated aluminum.

6 58. A sensor assembly as claimed in claim 55, wherein the housing further  
7 comprises:

8 a first rim having an inside and an outside, that is located on the periphery of the front  
9 of the housing;

10 a first indentation having an inside and an outside, that runs parallel and adjacent to  
11 the inside of the first rim;

12 a second indentation that runs parallel and adjacent to the inside of the first  
13 indentation;

14 a bore, that is approximately centrally located within the second indentation;

15 a second rim having an inside and an outside, that is located on the periphery of the  
16 back of the housing;

17 a third indentation having an inside and an outside, that runs parallel and adjacent to  
18 the inside of the second rim; and

19 a fourth indentation, that runs parallel and adjacent to the inside of the third  
20 indentation.

21 59. A sensor assembly as claimed in claim 58, wherein the electronic module nests  
22 within the bore.

23 60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is  
24 an "O" ring and the second shock dampener is an "O" ring.

25 61. A sensor assembly as claimed in claim 58, wherein the first mounting means is  
26 a plastic mounting ring and the second mounting means is a plastic mounting ring.

27 62. A sensor assembly as claimed in claim 58, wherein the first transducer is a  
28 piezoelement and the second transducer is a piezoelement.

29 63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling  
30 is a parametric acoustic transconductor and the second acoustic coupling is a parametric  
31 acoustic transconductor.

1           64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic  
2 transconductor comprises latex foam.

3           65. An apparatus for determining blood pressure comprising:  
4           an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic  
5 transmission coupling between skin and a piezoelectric transducer.

6           66. An apparatus for determining blood pressure as claimed in claim 65, wherein  
7 the acoustic coupling is a parametric acoustic transconductor.

8           67. An apparatus for determining blood pressure as claimed in claim 65, wherein  
9 the acoustic coupling has a high conduction coefficient.

10           68. An apparatus for determining blood pressure as claimed in claim 65 wherein  
11 the acoustic coupling comprises latex foam.

12           69. An apparatus for monitoring blood pressure comprising:  
13           an acoustic coupling;  
14           a transducer connected to the acoustic coupling;  
15           an electronic module connected to the transducer;  
16           a data acquisition module connected to the electronic module; and  
17           a data cable connected to the electronic module and the data acquisition module.

18           70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein  
19 the data cable is a twisted shielded pair.

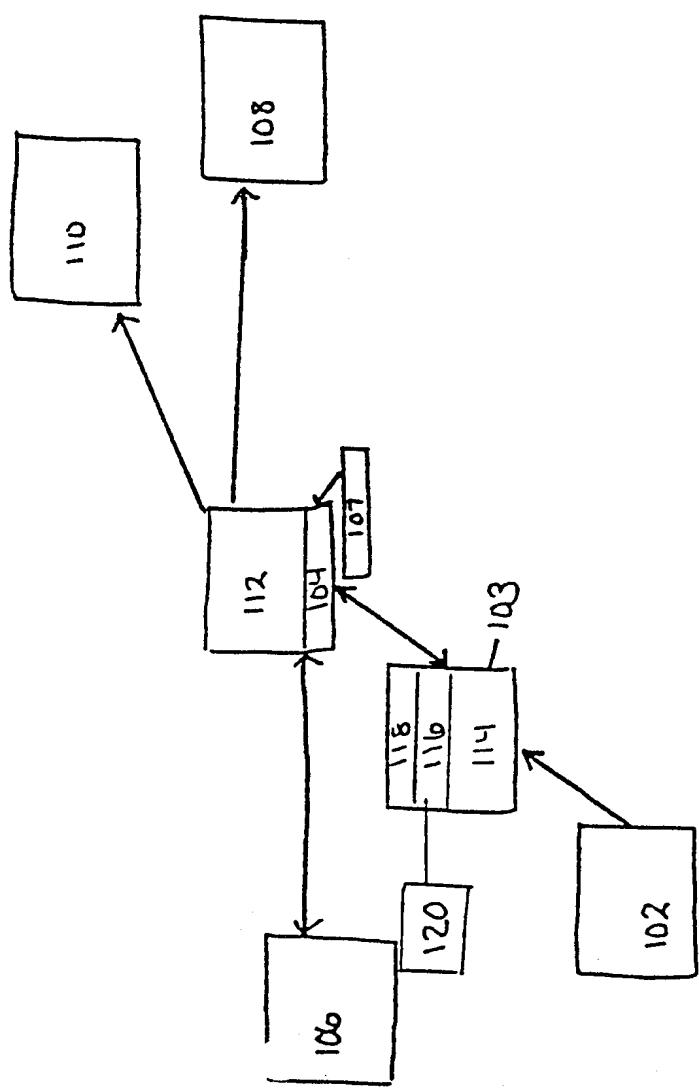
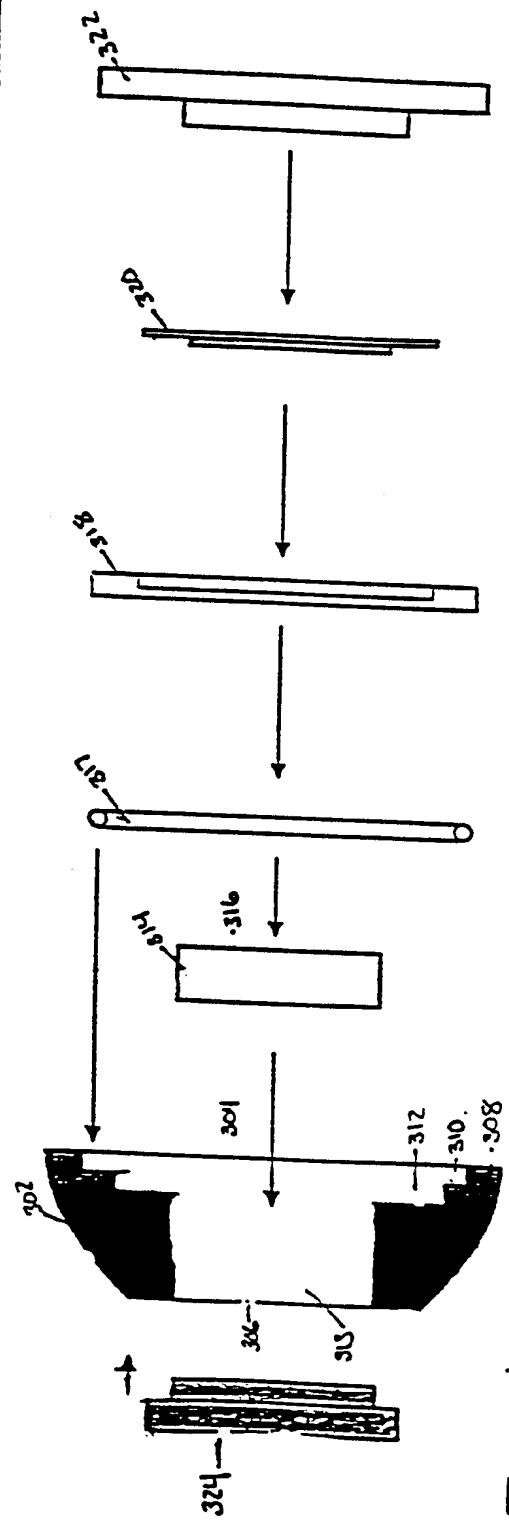
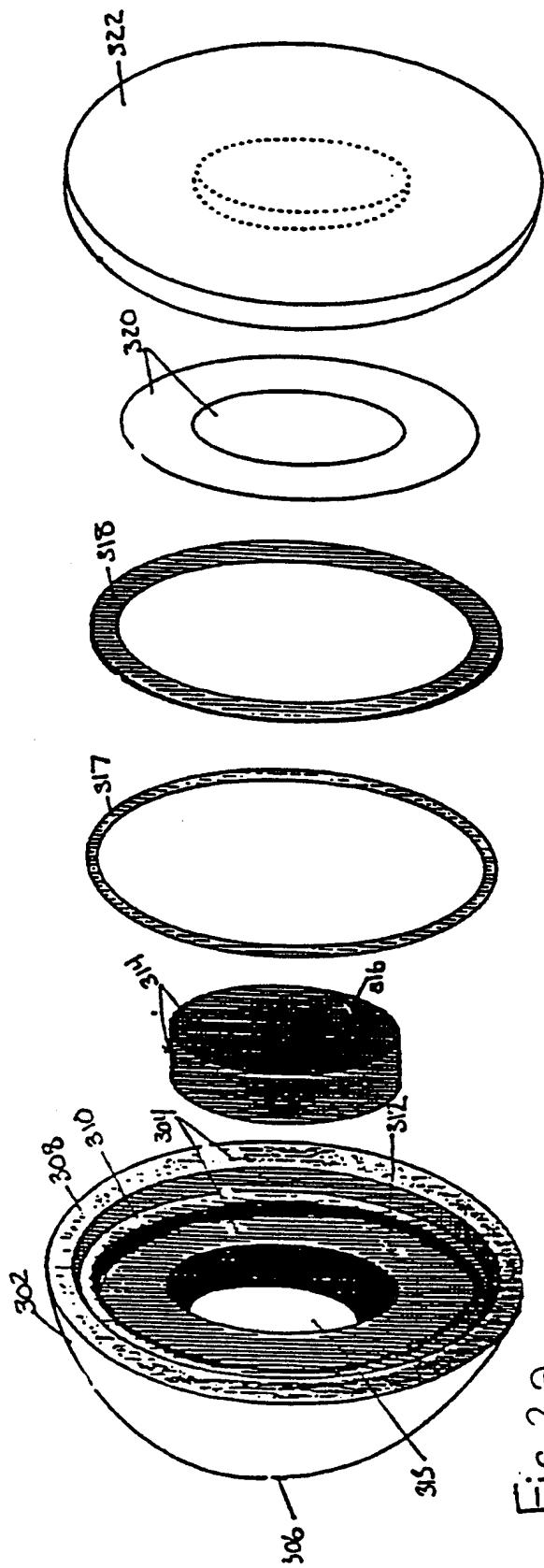


Fig. 1

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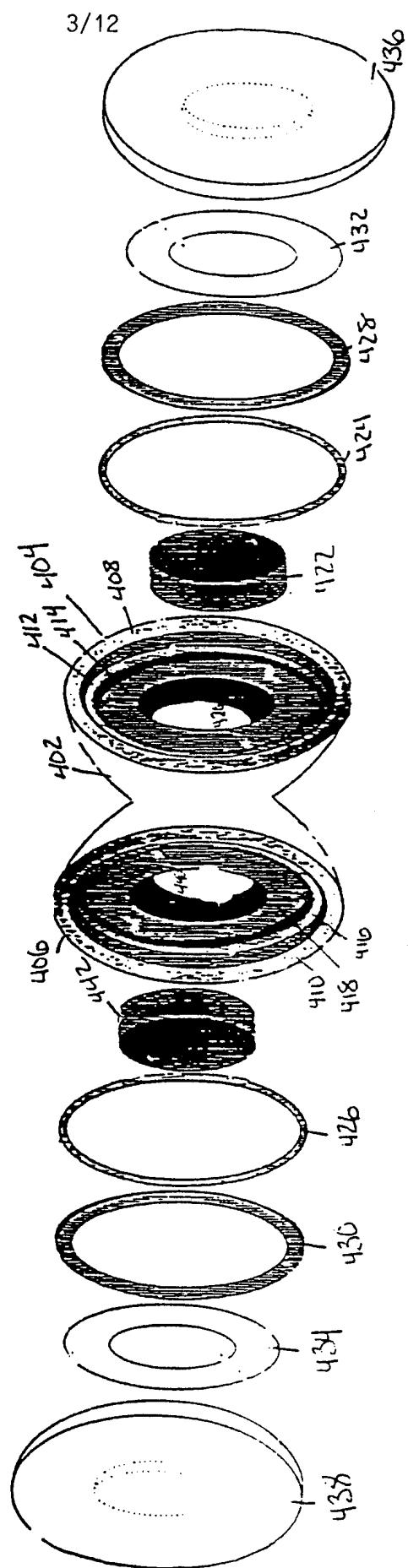


Fig. 3

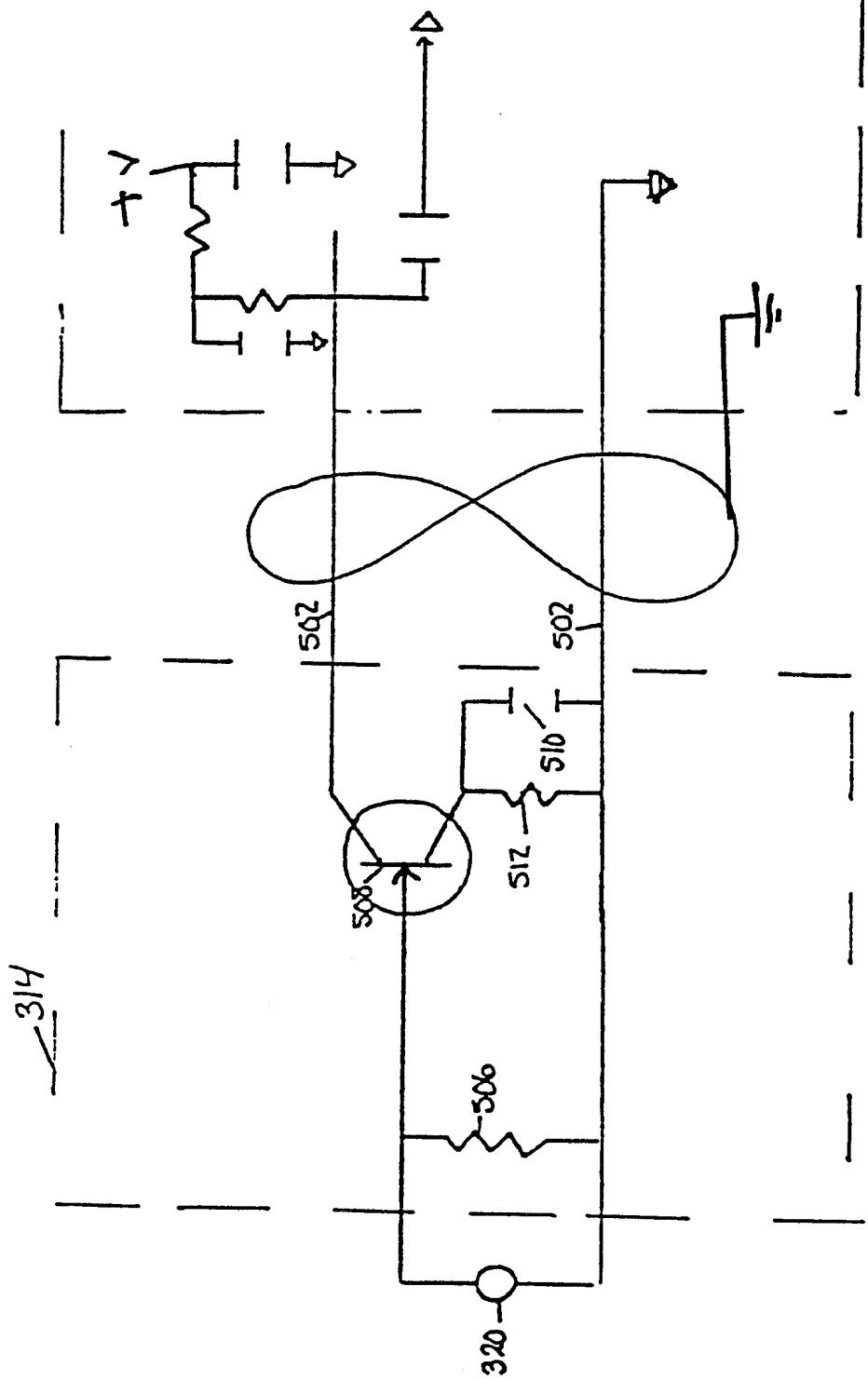
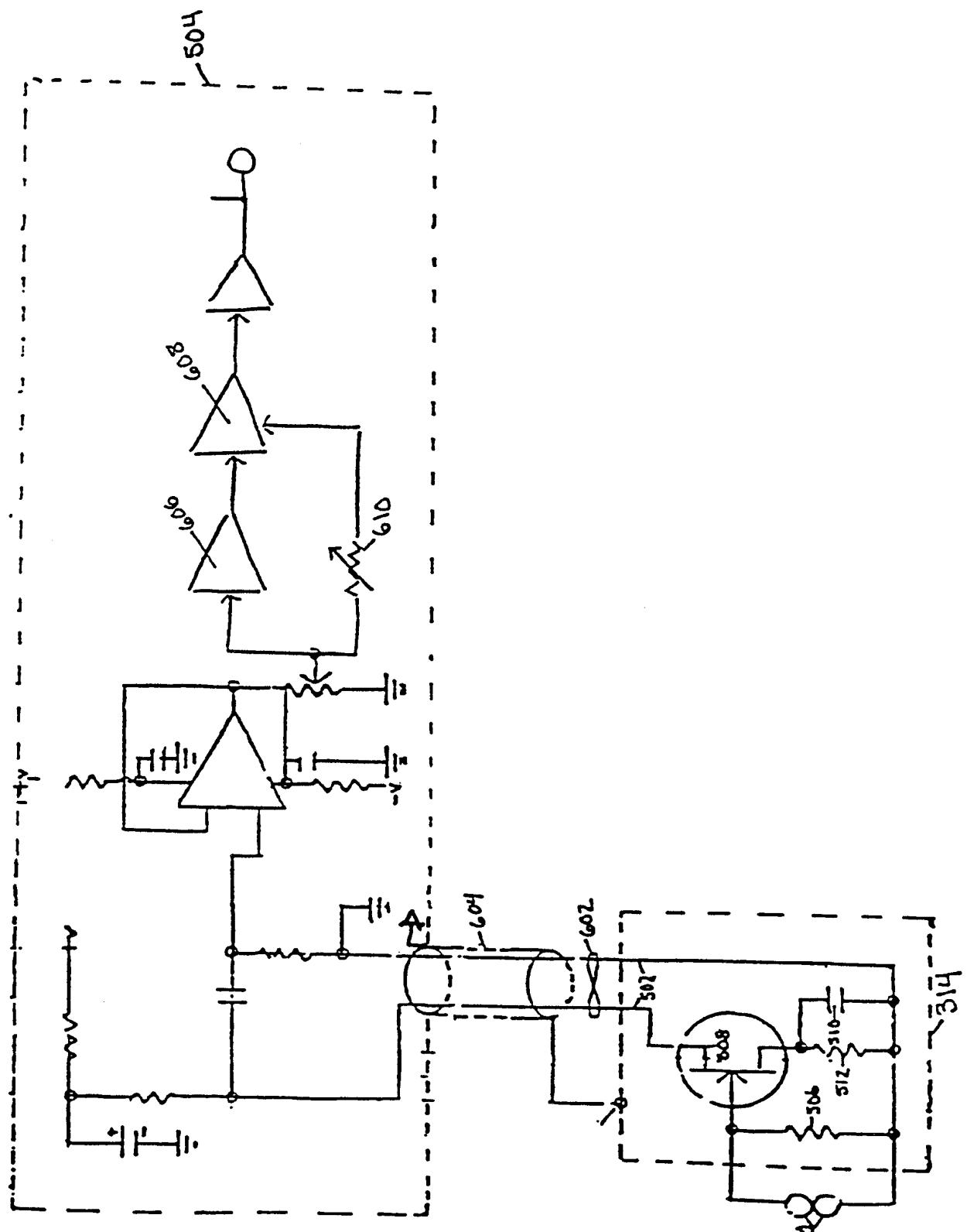
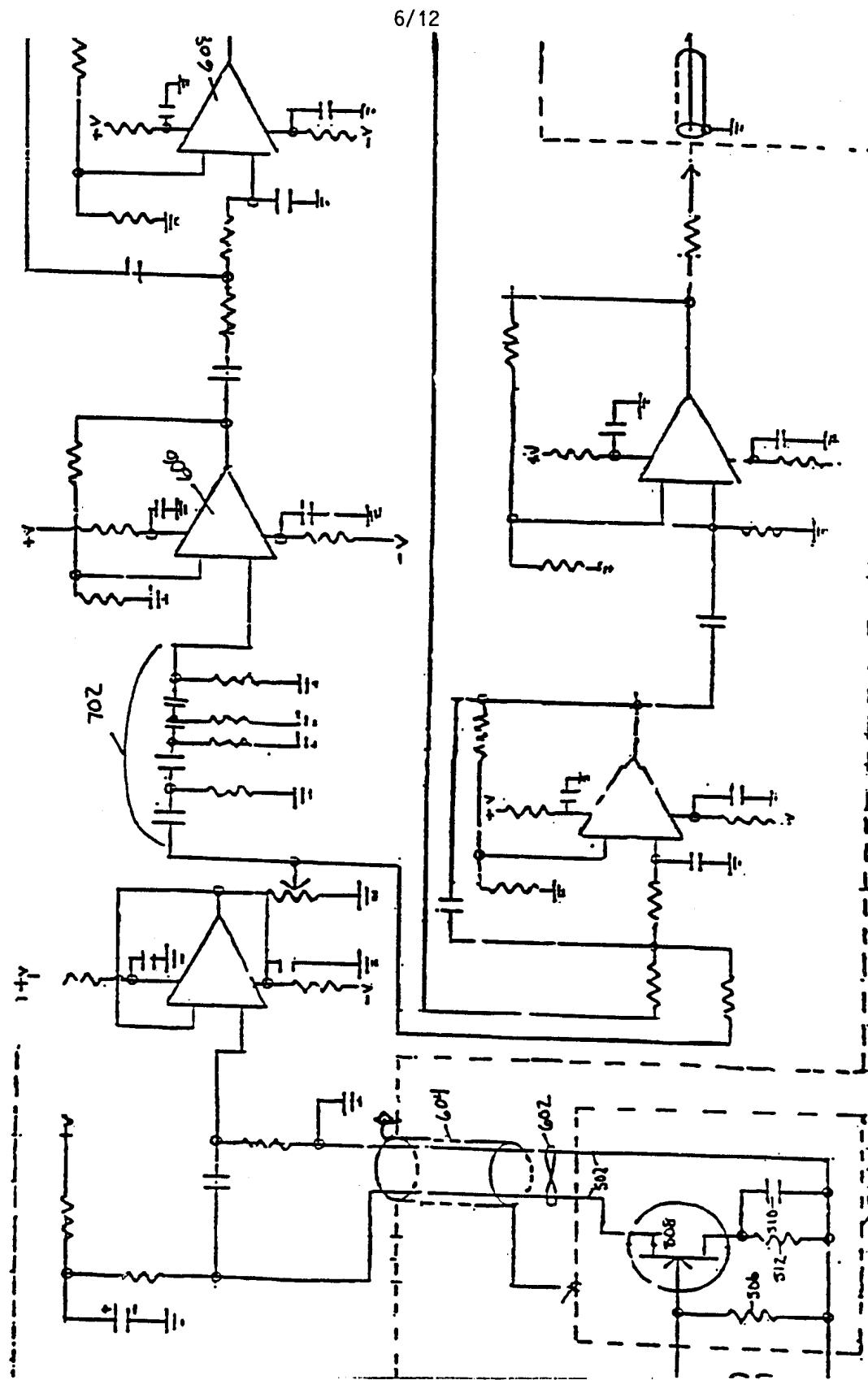


Fig. 4





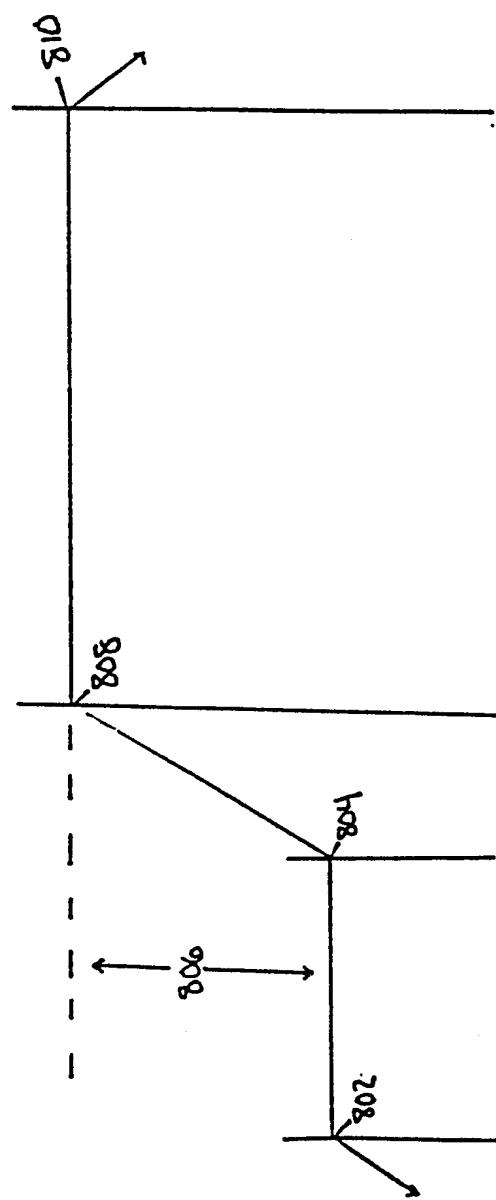
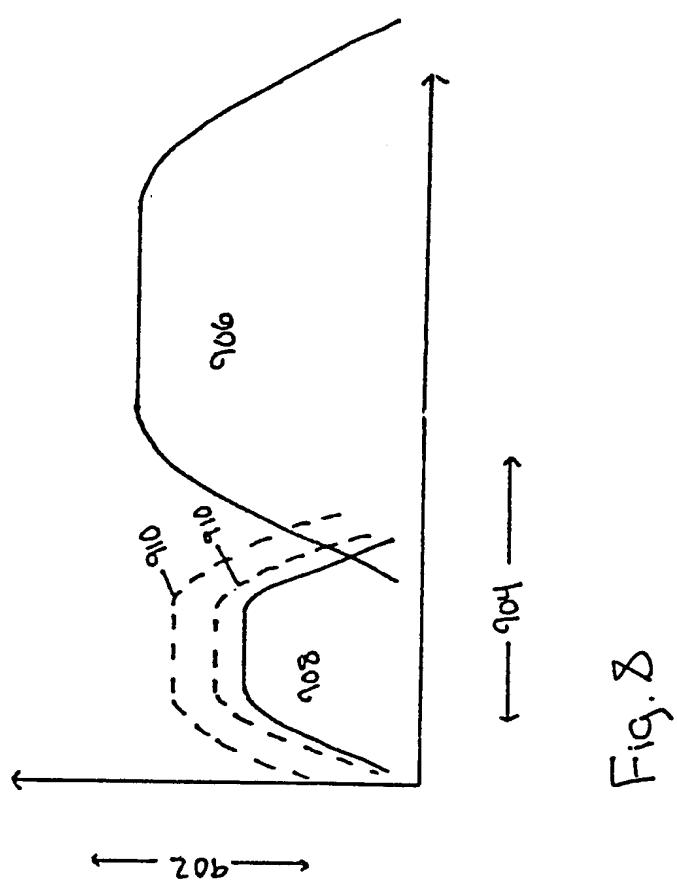
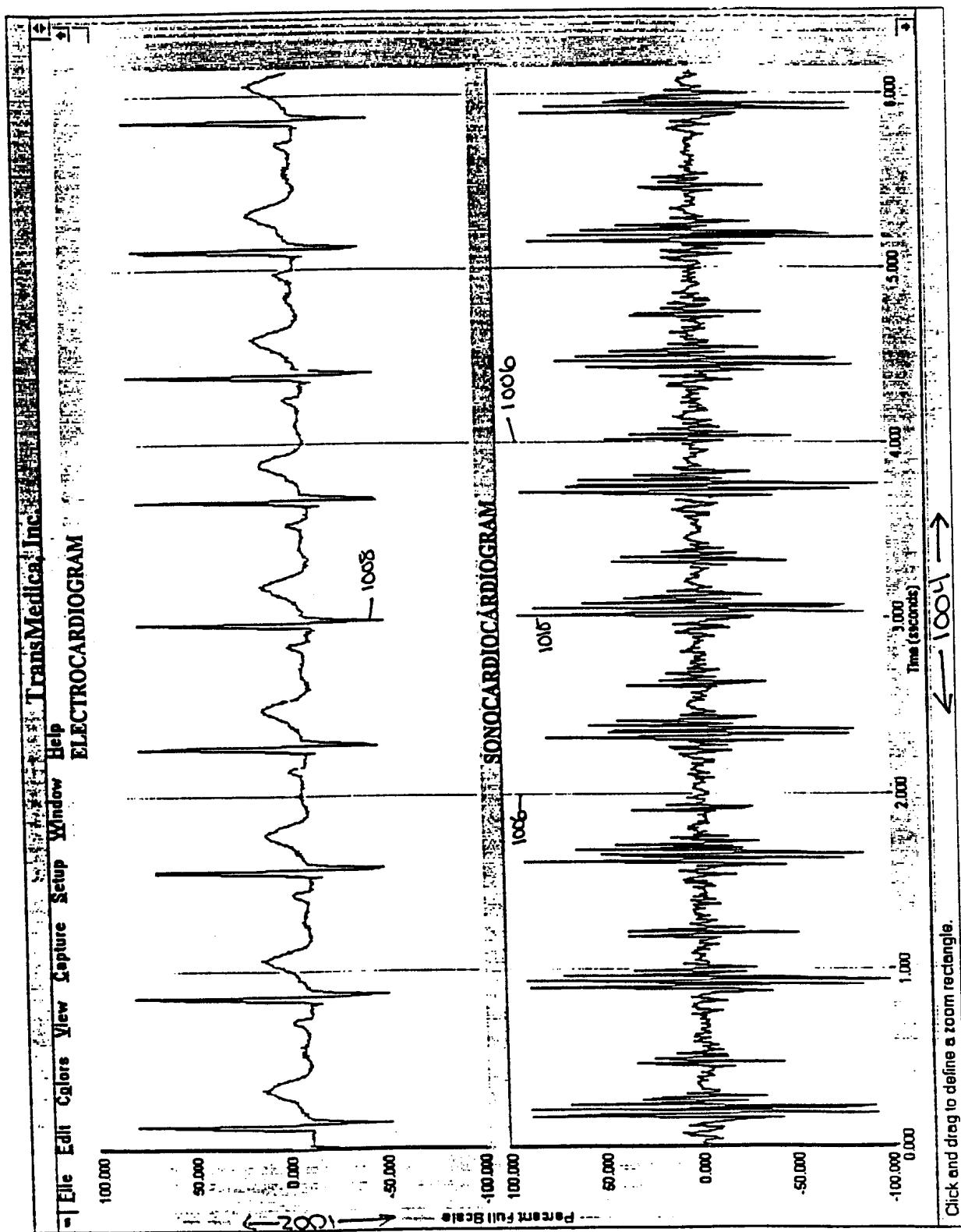
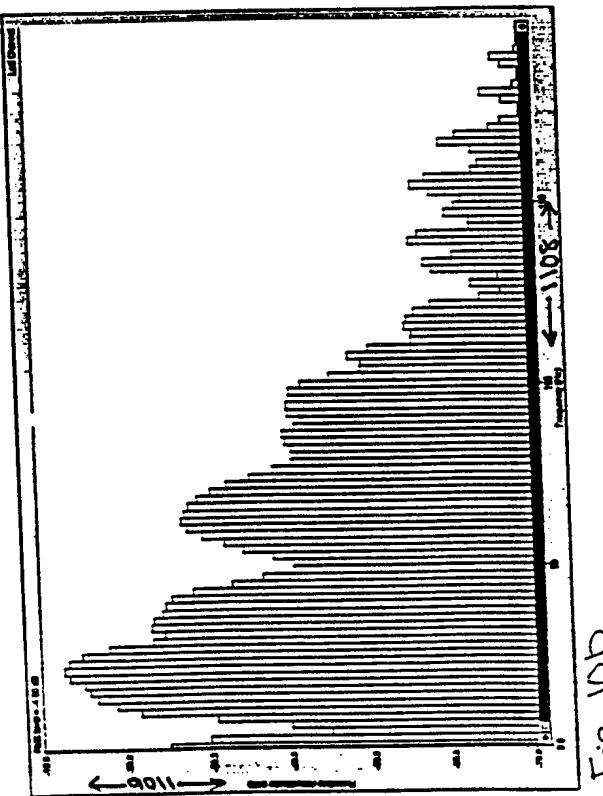
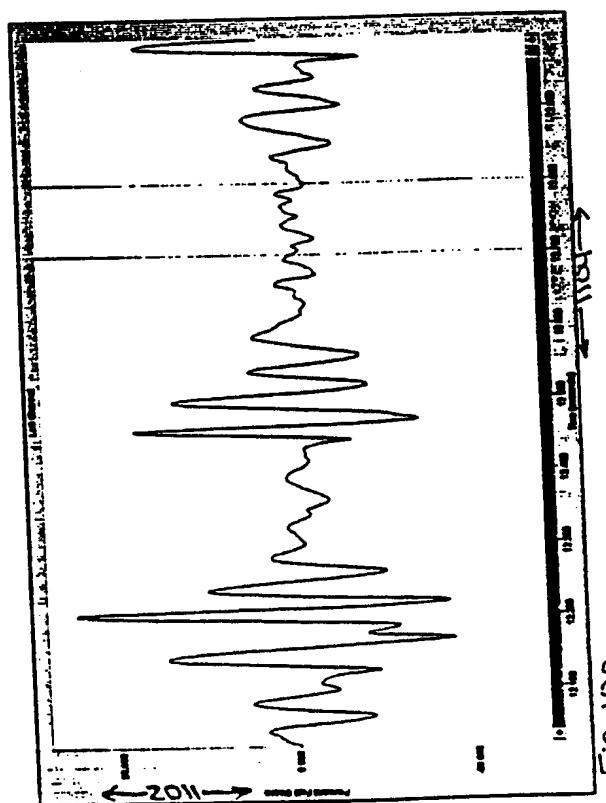
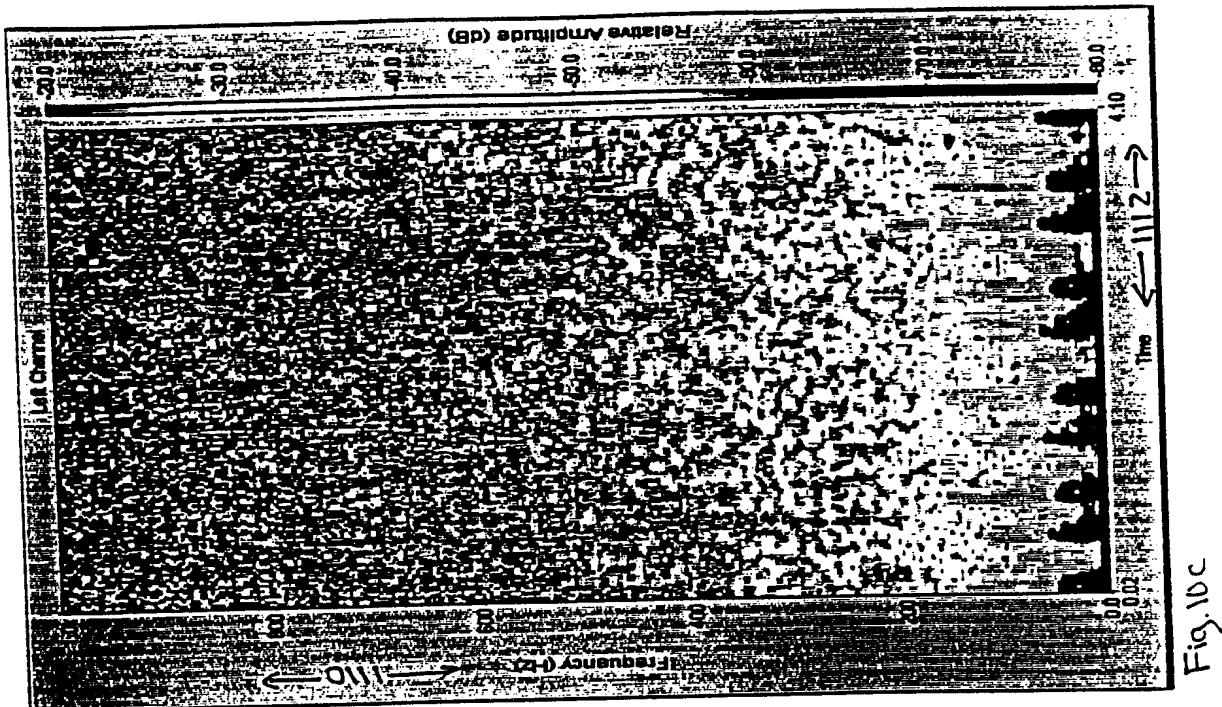


Fig. 7







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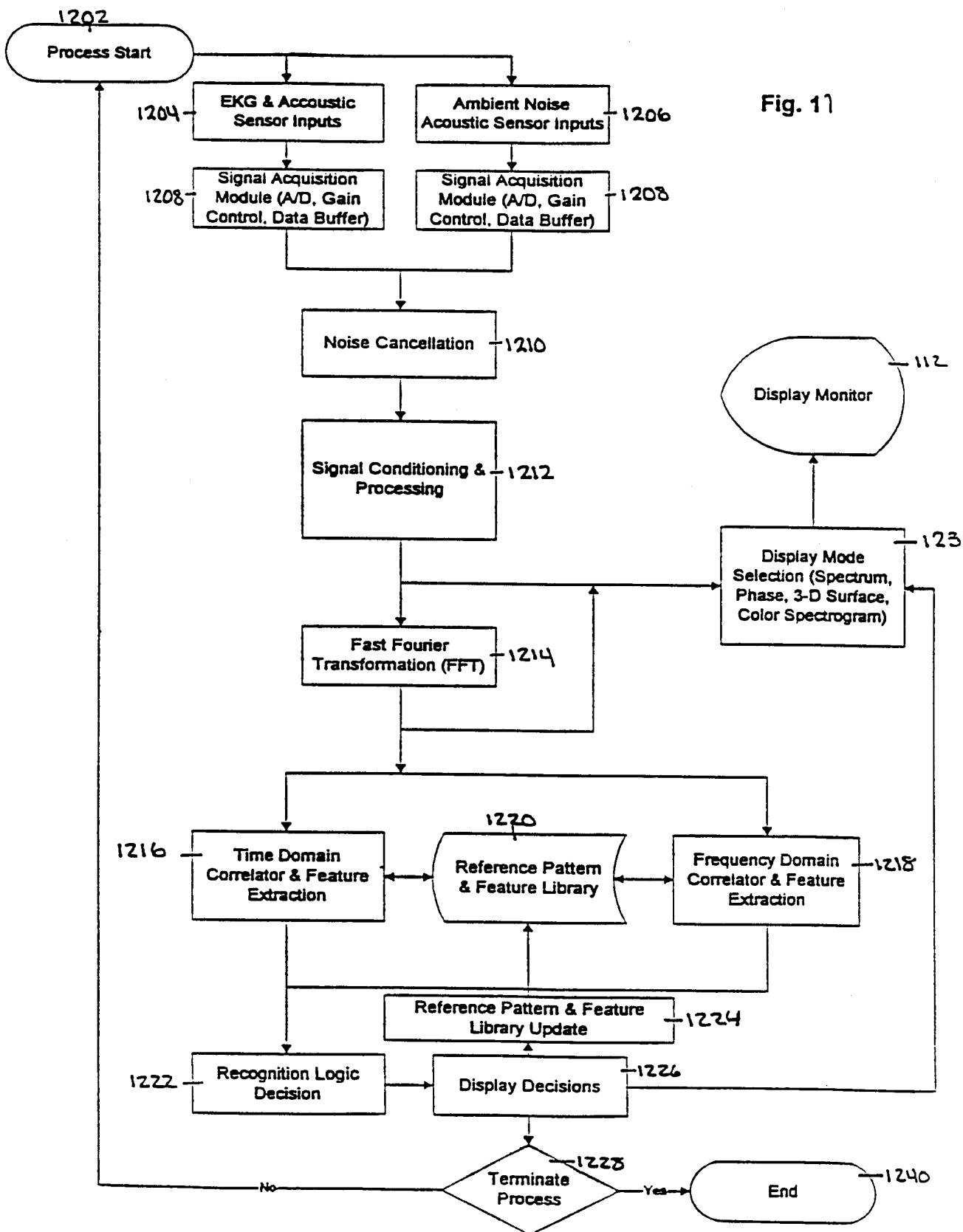
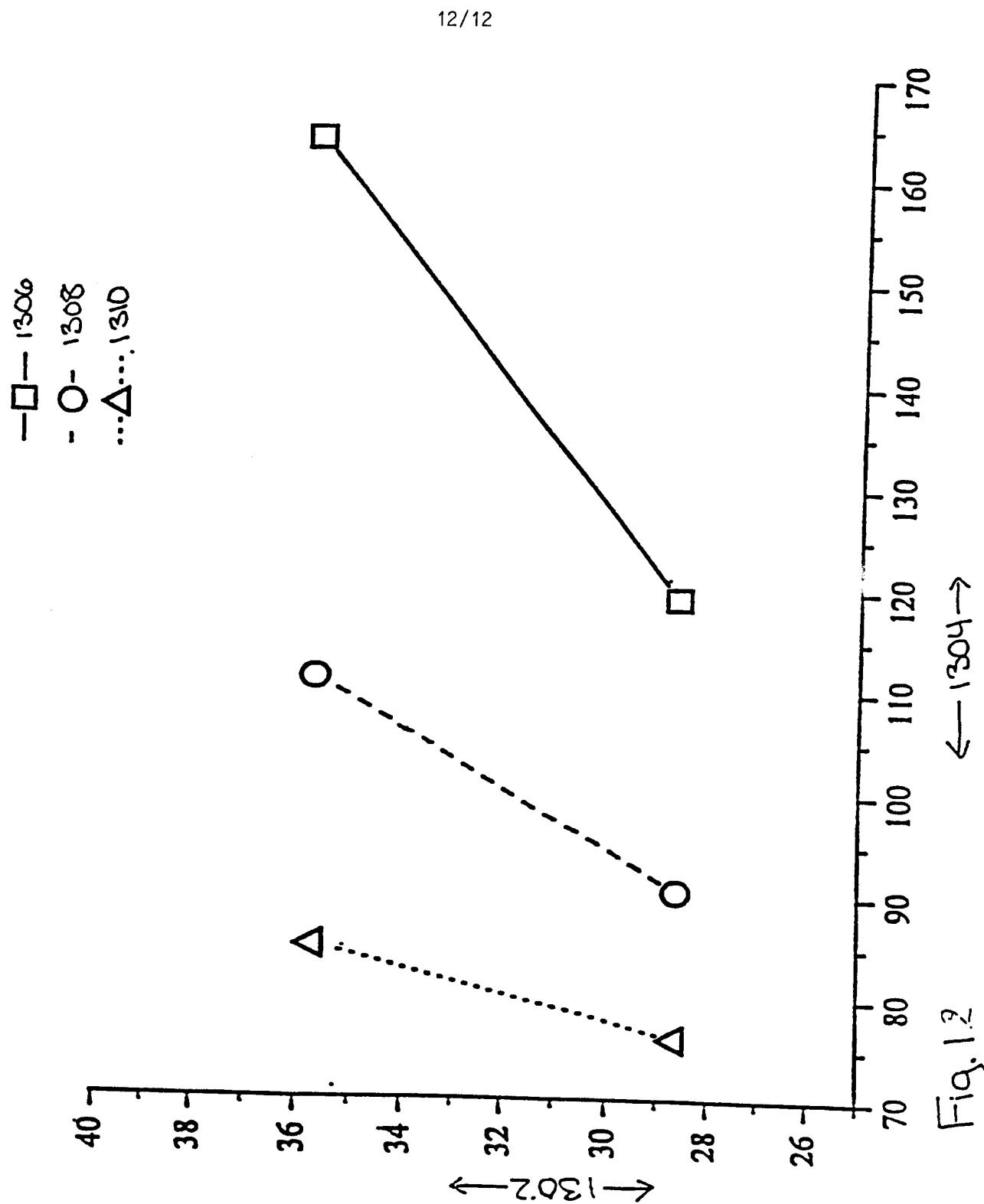


Fig. 11



# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21917

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B7/04

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category <sup>o</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPARI) 10 December 1980	1-4, 7, 9-11, 14, 25, 26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65, 69
A	see page 3, line 4 - line 37	6, 47, 55
A	see page 7, line 11 - page 9, line 18	57, 58
	see page 12, line 24 - page 17, line 17	---
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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PCT/US 97/21917	

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 467 775 A (T.F. CALLAHAN ET AL.) 21 November 1995	1-3,5, 10,14, 21, 25-28, 44-46, 48,51, 55,56,69
A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43,58
A	see column 8, line 5 - line 44	65,67
	see column 11, line 56 - column 12, line 55	-----
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A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36,39
A	see column 9, line 9 - column 10, line 45	40,43-46
A	see column 10, line 66 - column 11, line 24	55,56, 65,67,69
	see column 13, line 64 - column 15, line 31	-----
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A	see column 9, line 46 - column 11, line 44	36,38-42
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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

Int	national Application No
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 7/04</b>		A1	(11) International Publication Number: <b>WO 98/26716</b> (43) International Publication Date: 25 June 1998 (25.06.98)
(21) International Application Number: PCT/US97/21917			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 2 December 1997 (02.12.97)			
(30) Priority Data: 08/769,156 18 December 1996 (18.12.96) US			
(71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410 Lightening View, Columbia, MD 21045 (US).			
(74) Agent: ROBERTS, Jon, L.; Roberts & Brownell, L.L.C., Suite 212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).			
			<b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT			
(57) Abstract			
<p>An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low-loss acoustic transmission between the skin of the patient and the sensor assembly (102).</p>			
<pre> graph TD     Start((PROCESS START)) -- 1202 --&gt; EKG[EKG &amp; ACOUTIC SENSOR INPUTS]     Start -- 1202 --&gt; Amb[AMBIENT NOISE ACOUTIC SENSOR INPUTS]     EKG -- 1204 --&gt; SA1[SIGNAL ACQUISITION MODULE (A/D, GAIN CONTROL, DATA BUFFER)]     Amb -- 1206 --&gt; SA2[SIGNAL ACQUISITION MODULE (A/D, GAIN CONTROL, DATA BUFFER)]     SA1 -- 1208 --&gt; NC[NOISE CANCELLATION]     SA2 -- 1208 --&gt; NC     NC -- 1210 --&gt; SCP[Signal Conditioning &amp; Processing]     SCP -- 1212 --&gt; FFT[FAST FOURIER TRANSFORMATION (FFT)]     FFT -- 1214 --&gt; TDC[TIME DOMAIN CORRELATOR &amp; FEATURE EXTRACTION]     FFT -- 1214 --&gt; FDC[FREQUENCY DOMAIN CORRELATOR &amp; FEATURE EXTRACTION]     TDC -- 1216 --&gt; RPFL[REFERENCE PATTERN &amp; FEATURE LIBRARY]     FDC -- 1218 --&gt; RPFL     RPFL -- 1220 --&gt; RPFLU[REFERENCE PATTERN &amp; FEATURE LIBRARY UPDATE]     RPFLU -- 1222 --&gt; RL[RECOGNITION LOGIC DECISION]     RL -- 1226 --&gt; DD[DISPLAY DECISIONS]     DD -- 1228 --&gt; DM((DISPLAY MONITOR))     RL -- 1229 --&gt; End((END))   </pre>			

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**TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT**FIELD OF THE INVENTION

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

BACKGROUND OF THE INVENTION

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable alternative method of

1 monitoring blood pressure. This is extremely important in trauma patients where prompt  
2 detection of blood pressure changes are needed to counteract the effects of shock or large blood  
3 loss.

4 The pulmonic circuit provides for blood circulation from the right ventricle through the  
5 pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and  
6 posteriorly from the heart, dividing into right and left branches which serve the right and left  
7 lungs, respectively. Within the lungs the right and left branches of the pulmonary artery divide  
8 repeatedly giving rise to arterioles that continue into the capillary networks associated with the  
9 walls of the alveoli. Gas exchange occurs as the blood moves through these capillaries, so that  
10 when the blood enters the venules of the pulmonary circuit, it is well oxygenated and poor in  
11 carbon dioxide. The pulmonary venules merge forming small veins, which in turn converge  
12 forming larger veins. Four pulmonary veins return oxygenated blood to the left atrium, thereby  
13 completing the pulmonic circuit.

14 None of the arteries of the pulmonic system are located in extremities and therefore  
15 measurement of pulmonic system pressure with a blood pressure cuff is not possible.

16 At present, the only reliable method for measuring pulmonic system blood pressure is  
17 through use of an invasive blood pressure catheter that is inserted directly into the pulmonary  
18 artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is thus  
19 generally seen as an unjustified procedure in patients without other symptoms.

20 The physician may attempt to detect and differentiate the abnormal sounds that occur  
21 with elevated blood pressure using traditional auscultation. Closure of the aortic and pulmonary  
22 semilunar heart valves generate a sound component that is in the audio frequency range. As the  
23 systemic or pulmonic blood pressure increases, the frequency components of the related heart  
24 valve also increase. This increased frequency audio component is not present in a healthy  
25 patient. However, aural detection of this frequency increase is extremely difficult because the  
26 physician must determine the absolute frequency of the audio component of the heart valve of  
27 interest. Additionally, the sounds are very weak and heavily contaminated with noise from other  
28 patient heart sounds, other normal patient body sounds and external ambient noise in the room.  
29 Further, the audio component of the aortic and pulmonary semilunar heart valves are heavily  
30 attenuated as they pass through the patient's chest and chest wall.

31 A need exists for a non-invasive, low cost and reliable means for determining systemic

1 blood pressure in those situations where traditional means are contraindicated. A need also  
2 exists for a non-invasive, low cost and reliable means for determining pulmonary blood pressure.  
3

4 DESCRIPTION OF RELATED ART

5  
6 As mentioned, the sounds related to systemic and pulmonary heart pressure are difficult  
7 to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent No. 3,790,712  
8 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose relatively simple  
9 electronic stethoscopes as methods for amplification of the sounds in an attempt to raise the sub-  
10 audible components into the audible range. However, simple amplification of the entire  
11 frequency spectrum, as disclosed, does not help in determining the absolute frequency of the  
12 heart valve sounds, or in detecting the subtle changes of this frequency that occur with changes in  
13 blood pressure.

14 To this end, United States Patent No. 4,594,731 to Lewkowicz and United States Patent  
15 No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal processing  
16 on the audio signal in the electronic stethoscope. Lewkowicz discloses a means for shifting the  
17 entire detected spectrum of sounds upward while expanding the bandwidth so that they are more  
18 easily perceived by the listener. Dieken et al. discloses an electronic stethoscope having a greater  
19 volume of acoustic space and thereby improving low frequency response.

20 The electronic stethoscope provides a moderate improvement over conventional methods  
21 of auscultation. However, information remains in audio form only and is transient; the physician  
22 is unable to visualize the data and either freeze the display or focus on a particular element of the  
23 signal retrieved. To accommodate that deficiency, the technique of phonocardiography, which is  
24 the mechanical or electronic registration of heart sounds with graphic display, is used. United  
25 States Patent No. 5,218,969 to Bredesen et al.; United States Patent No. 5,213,108 to Bredesen  
26 et al.; United States Patent No. 5,012,815 to Bennett, Jr. et al.; United States Patent No.  
27 4,967,760 to Bennett, Jr. et al.; United States Patent No. 4,991,581 to Andries; and United States  
28 Patent No. 4,679,570 to Lund et al. disclose phonocardiography with signal processing and  
29 visual/audio output. United States Patent No. 5,301,679 to Taylor; and United States Patent No.  
30 4,792,145 to Eisenberg et al. disclose phonocardiography with signal processing and visual  
31 display.

1        The process of phonocardiography as commonly known in the art, acquires acoustic data  
2        through an air conduction microphone strapped to a patients chest, and provides the physician  
3        with a strip chart recording of this acoustic data. The strip chart is generally created at a rate of  
4        100 mm/second. As this method is generally used, with the exception of the created strip chart,  
5        data is not stored. Thus, it is not possible to manipulate and/or process the data post acquisition.  
6        In addition, phonocardiography does not provide the sensitivity needed to monitor softer  
7        physiological sounds such as the closure of the semilunar valves and blood flow through the  
8        circulatory system.

9        As previously noted, one problem in traditional auscultation is ambient noise from the  
10      room in which the examination is occurring, which reduces the signal-to-noise ratio of the  
11      sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for automatic  
12      lung sound cancellation and provides visual and audio output. United States Patent No.  
13      5,309,922 to Schecter et al. discloses a method for cancellation of ambient noise to enhance  
14      respiratory sounds and provides visual and audio output. United States Patent No. 5,492,129 to  
15      Greenberger discloses a method for reducing general ambient noise and provides audio output.

16        United States Patent No. 5,036,857 to Semmlow et al. discloses a method of  
17      phonocardiography with piezoelectric transducer. Semmlow specifically recommends against  
18      Fast Fourier Transformation analysis of the phonocardiography data and relies on processing by  
19      other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States Patent  
20      No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

21        United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory  
22      sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the  
23      sensors are not physically attached to the patient. Thus the sensors are not capable of detecting  
24      the low intensity sound of the aortic and pulmonary semilunar heart valves.

25        Devices currently known in the art do not provide either a means of determining systemic  
26      blood pressure where use of a blood pressure cuff is contraindicated, or a low risk, non-invasive  
27      means of determining pulmonic blood pressure. Additionally, the related art does not provide the  
28      level of aural sensitivity needed to reliably detect the sounds of the aortic and pulmonary  
29      semilunar heart valves and determine the precise frequency of these sounds.

30        What is needed is a safe, sensitive and noninvasive means of measuring systemic and/or  
31      pulmonic blood pressure. This is accomplished through the present invention. Through the use

1 of sonospectrography, a procedure based on integral spectral analysis techniques, systemic  
2 pressure can be monitored in conditions where traditional auscultation is contraindicated.  
3 Additionally, sonospectrography can be used to monitor pulmonic pressure in an inexpensive,  
4 noninvasive and low risk manner, allowing for the early detection of conditions such as cystic  
5 fibrosis, pleuresy, lung pulmonary diseases and pulmonary impedance. Sonospectrography is  
6 defined as the separation and arrangement of the frequency components of acoustic signals in  
7 terms of energy or time.

8 Further embodiments of the present invention provide a means of detecting physiological  
9 sounds, such as sounds emitted by the heart and other body organs as well as sounds related to  
10 the flow of blood through the circulatory system. Analysis of these sounds can be used to  
11 determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac  
12 output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as  
13 detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous  
14 thrombosis, intravascular blood clotting and carotid artery disease.

15

16 SUMMARY OF THE INVENTION

17

18 It is therefore an object of the present invention to provide an apparatus, operation and  
19 method for the detection and analysis of physiological sounds, such as sounds emitted by the  
20 heart and other body organs as well as sounds related to the flow of blood through the circulatory  
21 system.

22 It is a further object of the present invention to provide an apparatus, operation and  
23 method to be used to determine systemic and pulmonary blood pressure, monitor anesthesiology,  
24 determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal  
25 heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic  
26 decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery disease.

27 It is a further object of the present invention to provide this apparatus, operation and  
28 method through the use of sonospectrography.

29 It is a further object of the present invention to provide this apparatus, operation and  
30 method through a synchronized and coordinated combination of sonospectrography and  
31 electrocardiogram signals.

1        It is a further object of the present invention to provide this apparatus, operation and  
2        method through visual display means that provide insight to the subtle characteristics of the  
3        acoustic signature.

4        It is a further object of the present invention to provide this apparatus, operation and  
5        method through selective time and frequency windowing of the acoustic signals.

6        It is a further object of the present invention to provide this apparatus, operation and  
7        method through real-time signal processing or recorded-signal post processing.

8        It is a further object of the present invention to provide this apparatus, operation and  
9        method through use of single or multiple transducers.

10       It is a further object of the present invention to provide this apparatus, operation and  
11       method through a computer assisted search algorithm to identify optimal placement of the  
12       transducer(s) on the patient's chest wall.

13       It is a further object of the present invention to provide this apparatus, operation and  
14       method in office environments with moderate to high ambient noise levels, through adaptive  
15       noise cancellation techniques.

16       It is a further object of the present invention to provide this apparatus, operation and  
17       method in a form that provides for dynamic template building to facilitate disease detection and  
18       identification.

19       It is a further object of the present invention to provide this apparatus, operation and  
20       method through neural network techniques.

21       It is a further object of the present invention to provide an acoustic coupling that  
22       minimizes signal loss between the subject-detector interface and allows for the detection of  
23       sounds heretofore undetectable in a normal room environment.

24       It is a further object of the present invention to extend the ability of clinicians to analyze  
25       sounds which are lower in amplitude than those detectable by the unaided ear.

26       It is a further object of the present invention to extend the ability of clinicians to analyze  
27       sounds which are lower in frequency than those detectable by typical auscultation techniques.

28       It is a further object of the present invention to increase detection of a specified frequency  
29       range through the use of a tailored bandpass amplifier.

30       It is a further object of the present invention to provide a means for data storage, data  
31       manipulation and data transmission.

1        It is a further object of the present invention to provide this apparatus, operation and  
2        method through advanced processing of acoustic signatures in the time and frequency domain to  
3        isolate and display the sound components associated with pulmonary and/or aortic heart valve  
4        closure.

5        It is a further object of the present invention to provide an apparatus, operation and  
6        method that is suitable for routine physical examination screening and early diagnosis of elevated  
7        pulmonic blood pressure thereby providing an opportunity for early intervention to enhance the  
8        patient's productive life.

9        It is a further object of the present invention to provide an apparatus, operation and  
10       method that is suitable for monitoring of systemic blood pressure in patients where use of a  
11       traditional blood pressure cuff is contraindicated.

12       These and other objects of the present invention will become obvious to those skilled in  
13       the art upon review of the following disclosure.

14       An apparatus for determining blood pressure in accordance with the present invention  
15       includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a  
16       mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The sensor  
17       assembly is connected to a data acquisition module which in turn is connected to a signal  
18       processing means. The signal processing means is connected to an electronic storage means, a  
19       hard copy reproduction means, a remote connection means and a monitor. In an alternative  
20       embodiment of the invention a plurality of sensor assemblies are connected to the data  
21       acquisition module. In another alternative embodiment of the invention a means for determining  
22       an electrocardiogram is connected to the signal processing means. In yet another alternative  
23       embodiment of the invention, data acquisition module is connected to high-fidelity earphones.

24       The operation for determining blood pressure in accordance with the present invention  
25       includes:

- 26       1)       performing start-up procedures;
- 27       2)       acquiring physiologic signals;
- 28       3)       acquiring ambient or background signals;
- 29       4)       processing and subtracting ambient signals from physiologic signals;
- 30       5)       conditioning and processing resultant data;
- 31       6)       subjecting the conditioned and processed data to Fast Fourier Transformation;

- 1                   7) passing the time domain components of the data through a time domain correlator
- 2                   and feature extraction process;
- 3                   8) passing the frequency domain components of the data through a frequency domain
- 4                   correlator and feature extraction process;
- 5                   9) comparing the time domain output and the frequency domain output to a reference
- 6                   pattern and feature library;
- 7                   10) determining whether the time domain output and frequency domain output match
- 8                   known disease modalities;
- 9                   11) determining whether a disease modality is indicated;
- 10                  12) updating the reference pattern and feature library; and
- 11                  13) providing the information regarding the disease modality to the physician so that a
- 12                  treatment regimen may commence.

13                  The method for determining blood pressure in accordance with the present invention  
14                  includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where one  
15                  wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is done by  
16                  placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at the  
17                  traditional auscultation point for the aortic valve. Where one wishes to monitor pulmonary  
18                  pressure, the pulmonary semilunar valve is monitored. This is done by placing the acoustic  
19                  coupling of the sensor assembly in contact with the patient's skin at the traditional auscultation  
20                  point for the pulmonic valve. Detected signals are manipulated in the same fashion noted in the  
21                  "operation" of the present invention. The signals may be viewed and analyzed by medical  
22                  personnel at any number of points during this data manipulation process to allow for the  
23                  implementation of a treatment regimen. Where the sound emitted by either semilunar valve is of  
24                  a higher than normal frequency, this is indicative of increased blood pressure in the  
25                  corresponding circuit; that is, an increased frequency emitted by the aortic semilunar valve is  
26                  indicative of higher than normal systemic blood pressure, while an increased frequency being  
27                  emitted by the pulmonary semilunar valve is indicative of higher than normal pulmonary blood  
28                  pressure.

29

30                  BRIEF DESCRIPTION OF THE DRAWINGS

31

Figure 1 is a schematic representation of the overall architecture and user interface of the present invention.

Figure 2a depicts an exploded, oblique view of the sensor assembly.

Figure 2b depicts an exploded, side view of the sensor assembly.

Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor assembly.

Figure 4 depicts a circuit diagram of the electronic module, data cable and data acquisition module.

Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic module, data cable and data acquisition module.

Figure 7 depicts the frequency response of a tailored bandpass amplifier.

Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

Figure 9a illustrates an acoustic amplitude vs. time display mode.

Figure 9b illustrates a relative amplitude vs. frequency display mode.

Figure 9c illustrates a frequency vs. time display mode.

Figure 10 is a flow chart illustrating the operation of the present invention.

Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.

### DETAILED DESCRIPTION

The present invention provides an apparatus, operation and method to passively and non-invasively measure systemic and pulmonic blood pressure through detection, identification and characterization of the acoustic signature associated with heart valve closure.

## APPARATUS

Referring to Figure 1, the overall architecture of the present invention is described. Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by sensor assembly 102. In an alternative embodiment a plurality of sensor assemblies can be used.

1 to either simultaneously obtain signals from various locations of the body or to simultaneously  
2 obtain signals from both the patient and the environment. Sensor assembly **102** is connected to  
3 data acquisition means **103**.

4 Data acquisition means **103** comprises preamplifier **114**, audio amplifier **116**, and analog-  
5 to-digital converter **118**. Preamplifier **114** electronically isolates the transducer, detects the  
6 electronic signals, and sends them to audio amplifier **116** and to analog-to-digital converter **118**.  
7 Audio amplifier **116** drives one or more sets of high-fidelity earphones **120**. Analog-to-digital  
8 converter **118** samples the analog signal and converts it to a binary number for each time sample.  
9 Data acquisition means **103** is connected to signal processing means **104**.

10 Signal processing means **104** is a general-purpose microprocessor. Signal processing  
11 means **104**, also has means for video display of information, such as monitor **112**. Signal  
12 processing means **104** is connected to electronic data storage means **106**, operator input means  
13 **107**, hard copy reproduction means **108** and remote connection means **110**.

14 Various types of electronic data storage are known to those skilled in the art. In  
15 alternative embodiments electronic data storage means **106** comprises: internal hard disk drive,  
16 external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM.  
17 Likewise, various types of operator input means are known to those skilled in the art. In  
18 alternative embodiments operator input means **107** comprises: keyboard, mouse, voice detector  
19 or other means. Hard copy reproduction means **108** provides copies of images displayed on  
20 monitor **112** for purposes such as maintaining medical records, assisting consultations, and  
21 assisting data processing and review. Remote connection means **110** is a modem. In alternative  
22 embodiments, the system of the present invention may be directly linked to a network via a  
23 network interface card or other suitable means. Thus a modem may not always be necessary.

24 In an alternative sensor assembly embodiment, sensor assembly **102** can detect both  
25 physiologic and background signals. In another alternative sensor assembly embodiment, one  
26 side of sensor assembly **102** comprises an audio transducer which is in contact with the skin  
27 while a second audio transducer on the opposite side faces away from the patient. This second  
28 transducer is designed to acquire ambient sounds in synchronism with the sounds reaching the  
29 transducer in contact with the patient's skin to reject common mode signals reaching both  
30 transducers. By adding the environmental signals out of phase with the signals acquired from the

1 patient, the sounds in common to both transducers are effectively canceled. In yet another  
2 alternative sensor assembly embodiment the target frequency range for data acquisition is about  
3 200 to 2000 Hz. In another alternative sensor assembly embodiment, the target frequency range  
4 for signal acquisition is about 400 hertz.

5 In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise data  
6 acquisition and proper impedance matching.

7 In an alternative analog-to-digital converter embodiment analog-to-digital converter **118**  
8 has a sample rate about 4 to 48 KHz. In yet another alternative analog-to-digital converter  
9 embodiment, analog-to-digital converter **118** has a sample rate of about 44 KHz. In another  
10 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a  
11 resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment,  
12 analog-to-digital converter **118** has a linearity about  $\pm 0.005$  percent of full scale. In another  
13 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample  
14 length of about one to sixty seconds. In yet another alternative analog-to-digital converter  
15 embodiment, analog-to-digital converter **118** has an operator selectable sample length.

16 In an alternative earphones embodiment, earphones **120** have separate volume controls.

17 In an alternative signal processing means embodiment, signal processing means **104** is a  
18 computer with a central processing unit. In another alternative signal processing means  
19 embodiment, signal processing means **104** is an IBM compatible personal computer using an  
20 INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a  
21 minimum hard disk size of 500 MB. In yet another alternative signal processing means  
22 embodiment, signal processing means **104** is a Macintosh PowerPC.

23 In an alternative monitor embodiment, monitor **112** has a minimum display size of 600 X  
24 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another alternative  
25 monitor embodiment, monitor **112** is a high resolution EGA or VGA color display monitor.

26 In an alternative signal processing means embodiment, signal processing means **104**  
27 comprises a sound card. In another alternative signal processing means embodiment, the sound  
28 card comprises a "Tahiti" multiple channel computer sound card manufactured by Turtle Beach,  
29 although sound cards such as the Pro Audio 1b (Media Vision) can also be used.

30 In an alternative hard copy reproduction means embodiment, hard copy reproduction

1 means 108, is a printer. In another alternative hard copy reproduction means embodiment, hard  
2 copy reproduction means 108 is a printer capable of generating a variety of different graphic  
3 displays. In yet another alternative hard copy reproduction means embodiment, hard copy  
4 reproduction means 108 is a laser printer.

5 In an alternative remote connection means embodiment, remote connection means 110 is  
6 an internal or external, high speed modem. In another alternative remote connection means  
7 embodiment, remote connection means 110 has a speed of at least 14.4 kilobytes per second.

8 Referring to Figure 2a, an oblique view of an embodiment of sensor assembly 102 is  
9 shown. Figure 2b depicts a side view of an embodiment of sensor assembly 102. Housing 302  
10 comprises a sound deadening material having sufficient mass to dampen high frequency ambient  
11 disturbances and hold the sensor assembly in contact with the patient through gravity. Housing  
12 302 has housing front 304 and housing back 306. Rim 308 is located on the periphery of housing  
13 front 304. First indentation 310 runs parallel and adjacent to the inside of rim 308. Second  
14 indentation 312 runs parallel and adjacent to the inside of first indentation 310. Bore 312 is  
15 approximately centrally located within second indentation 312 and is shaped and sized in  
16 conformity to the shape and size of electronic module 314. Electronic module 314 nests within  
17 bore 312 of housing 302. As will be further discussed, signal detection and processing circuitry  
18 are incorporated within electronic module 314.

19 Shock dampener 316 is positioned adjacent to first indentation 310. Mounting means 318  
20 is positioned adjacent to shock dampener 316. Transducer 320 is positioned within mounting  
21 means 318. Transducer 320 converts detected signals into electronic signals. Acoustic coupling  
22 322 is positioned adjacent to transducer 320. Acoustic coupling 322 serves to dilinearize  
23 excitation response and reduce dynamic range.

24 Once assembled, housing 302 is closed to the ambient environment with back cover 324.  
25 Sensor assembly 102 comprising all the individual sensor elements, is assembled and sealed to  
26 form a single complete unit.

27 In an alternative housing embodiment, housing 302 is composed of nickel plated  
28 aluminum, but can be any material having sufficient mass to dampen high frequency ambient  
29 disturbances and hold the sensor in contact with the patient through gravity.

30 In an alternative sensor assembly embodiment, when electronic module 314 nests within

1 bore **312** of housing **302**, top **316** of electronic module **314** is flush with second indentation **312**.

2 In an alternative shock damper embodiment shock damper **316** is an "O" ring.

3 In an alternative mounting means embodiment, mounting means **318** is a plastic  
4 mounting ring.

5 In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In  
6 another alternative transducer embodiment, transducer **320** has a high impedance. In yet another  
7 alternative transducer embodiment, transducer **320** has an impedance of about 470 Kohms. In  
8 another alternative transducer embodiment, transducer **320** has high efficiency as compared with  
9 conventional electromagnet type speakers. In yet another alternative transducer embodiment,  
10 transducer **320** is ultra thin and lightweight. In another alternative transducer embodiment,  
11 transducer **320** has a frequency range of about 500 - 20,000 Hz. In yet another alternative  
12 transducer embodiment, transducer **320** has a capacitance at 120 Hz of about  $60 \pm 30 \text{ } \mu\text{F}$ . In  
13 another alternative transducer embodiment, transducer **320** current leakage is limited to about  
14 one micro ampere.

15 In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance  
16 matched, and serves to provide a low-loss acoustic transmission coupling between the skin of the  
17 patient and transducer **320**, thereby minimizing signal loss across the subject-detector interface.  
18 In another alternative acoustic coupling embodiment, acoustic coupling **322** is a parametric  
19 acoustic transconductor. In yet another acoustic coupling embodiment, acoustic coupling **322**  
20 has a high conduction coefficient. In another alternative acoustic coupling embodiment, acoustic  
21 coupling **322** is made of latex foam. In yet another alternative acoustic coupling embodiment,  
22 acoustic coupling **322** is logarithmically attenuated, having low transmission at low frequencies  
23 and high transmission at high frequencies.

24 Referring to Figure 3 an oblique exploded view of an alternative embodiment of sensor  
25 assembly **102** is shown. Housing **402** comprises a sound deadening material having sufficient  
26 mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact  
27 with the patient through gravity. Housing **402** has housing front **404** and housing back **406**. First  
28 rim **408** is located on the periphery of housing front **404**. Second rim **410** is located on the  
29 periphery of housing back **406**. First indentation **412** runs parallel and adjacent to the inside of  
30 first rim **408**. Second indentation **414** runs parallel and adjacent to the inside of first indentation

1       **412.** Third indentation **416** runs parallel and adjacent to the inside of second rim **410**. Fourth  
2       indentation **418** runs parallel and adjacent to the inside of third indentation **416**. First bore **420** is  
3       approximately centrally located within second indentation **414** and is shaped and sized in  
4       conformity to the shape and size of first electronic module **422**. Second bore **440** is  
5       approximately centrally located within fourth indentation **418** and is shaped and sized in  
6       conformity to the shape and size of second electronic module **442**. First electronic module **422**  
7       nests within first bore **420** of housing **402**. Second electronic module **442** nests within second  
8       bore **440** of housing **402**. As will be further discussed, signal detection and processing circuitry  
9       are incorporated within first and second electronic module **422, 442**.

10       First shock dampener **424** is positioned adjacent to first indentation **412**. Second shock  
11       dampener **426** is positioned adjacent to third indentation **416**. First mounting means **428** is  
12       positioned adjacent to first shock dampener **424**. Second mounting means **430** is positioned  
13       adjacent to second shock dampener **426**. First transducer **432** is positioned within first mounting  
14       means **428**. Second transducer **434** is positioned within second mounting means **430**. First  
15       transducer **432**, converts detected physiologic signals into electronic signals. Second transducer  
16       **434**, converts detected environmental or background signals into electronic signals. First  
17       acoustic coupling **436** is positioned adjacent to first transducer **432**. Second acoustic coupling  
18       **438** is positioned adjacent to second transducer **434**. First and second acoustic coupling **436, 438**  
19       serve to dilinearize excitation response and reduce dynamic range.

20       In an alternative housing embodiment, housing **402** is composed of nickel plated  
21       aluminum.

22       In an alternative shock dampener embodiment, first and second shock dampener **424, 426**  
23       is an "O" ring.

24       In an alternative mounting means embodiment, first and second mounting means **428,**  
25       **430** is a plastic mounting ring.

26       In an alternative transducer embodiment, first and second transducer **432, 434** is a  
27       piezoelectric disk. In another alternative transducer embodiment, first and second transducer  
28       **432, 434** has a high impedance. In yet another alternative transducer embodiment, first and  
29       second transducer **432, 434** has an impedance of about 470 Kohms. In another alternative  
30       transducer embodiment, first and second transducer **434, 434** has high efficiency as compared

1 with conventional electromagnet type speakers. In yet another alternative transducer  
2 embodiment, first and second transducer **432, 434** is ultra thin and lightweight. In another  
3 alternative transducer embodiment, first and second transducer **432, 434** has a frequency range  
4 of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and second  
5 transducer **432, 434** has a capacitance at 120 Hz of about  $60 \pm 30$  % nF. In another alternative  
6 transducer embodiment, first and second transducer **432, 434** current leakage is limited to about  
7 one micro ampere.

8 In an alternative acoustic coupling embodiment, first and second acoustic coupling **436,**  
9 **438**, is impedance matched, and serves to provide a low-loss acoustic transmission coupling  
10 between the skin of the patient and first transducer **432**, thereby minimizing signal loss across the  
11 subject-detector interface. In another alternative acoustic coupling embodiment, first and second  
12 acoustic coupling **436, 438** is a parametric acoustic transconductor. In yet another acoustic  
13 coupling embodiment, first and second acoustic coupling **436, 438** has a high conduction  
14 coefficient. In another alternative acoustic coupling embodiment, first and second acoustic  
15 coupling **436, 438** is made of latex foam. In yet another alternative acoustic coupling  
16 embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low  
17 frequencies and high transmission at high frequencies.

18 Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data  
19 acquisition module **504** of the present invention are shown in schematic form. In combination,  
20 first resistor **506**, semiconductor device **508**, second resistor **510**, and first capacitor **512**  
21 comprise electronic module **314**. Electronic module **314** performs functions such as signal  
22 amplification, and filtering. Transducer **320** is connected in parallel with first resistor **506**,  
23 second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor **508** serves to  
24 modulate current. First capacitor **512** provides gain and source decoupling for semiconductor  
25 **508**.

26 In an alternative first resistor embodiment, first resistor **506** provides a matching load to  
27 transducer **320**. In another alternative first resistor embodiment first resistor **506** has a resistance  
28 of 470 Kohms.

29 In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

30 In an alternative semiconductor embodiment, semiconductor **508** is field effect transistor.

1 In another alternative semiconductor embodiment, semiconductor **508** is a field effect transistor  
2 with an N-type base.

3 In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and is  
4 connected to ground.

5 Figure 5 depicts a circuit diagram of the electronic module, data cable and data  
6 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer  
7 **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic module  
8 **314** to data acquisition module **504**. Data acquisition module **504** comprises an amplifier. As  
9 depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having a DC injection  
10 point. The amount of DC injection is made variable by value selection of variable resistor **610**.  
11 In an alternative value selection embodiment, value selection is determined by the practitioner.  
12 In yet another alternative value selection embodiment, value selection is determined  
13 automatically by the signal processing means in conformity with predetermined parameters.

14 In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein two  
15 insulated wires are twisted forming a flexible line without the use of spacers. In another  
16 alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel  
17 conductors are separated from each other and surrounded by a solid dielectric. In this alternative  
18 embodiment, the conductors are contained within a copper-braid tubing that acts as a shield. The  
19 assembly is covered with a rubber or flexible composition coating to protect the line against  
20 moisture and friction. There are two advantages of this alternative embodiment: (1) the  
21 capacitance between each conductor and ground is uniform along the entire length of the line;  
22 and (2) the wires are shielded against pickup of stray electric fields. In yet another alternative  
23 embodiment shielded pair **604** data cable **502** is connected to sensor housing **610** and to ground  
24 as a means for reducing electrical noise and increasing patient safety.

25 In an alternative data acquisition module embodiment, data acquisition module **504** has a  
26 low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a level 20 dB  
27 higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In another  
28 alternative data acquisition module embodiment, data acquisition module **504** comprises a  
29 voltage gain, variable from zero to fifty, allowing recovery of low-level sounds from 600 to about  
30 2000 Hz while preserving the ability to measure low-frequency signals having a relatively high

1 amplitude, without amplifier saturation.

2 In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7,  
3 and lowpass filter **608** drives an output amplifier with a gain of about 7. In another alternative  
4 highpass filter embodiment the overall voltage gain available with the gain potentiometer at  
5 maximum will be about 50. An advantage of this alternative embodiment is the ability to reject a  
6 narrow range of frequencies in a notch caused by the phase delay in the components of highpass  
7 filter **606**. In an alternative highpass filter embodiment this notch is set at 100 Hz. In another  
8 alternative highpass filter embodiment this notch is set at about 50 - 60 Hz, thereby providing a  
9 measure of hum rejection

10 Figure 6 depicts a circuit diagram of the electronic module, data cable and data  
11 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer  
12 **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network **702**  
13 gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz that is  
14 related to the combined resistor/capacitor time constants of the network. Field effect transistor  
15 **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-type  
16 operational amplifier pair.

17 Figure 7 depicts an idealized shape of an amplifier having low-frequency response from  
18 first point **802** to crossover point **804** and having higher frequency response of predetermined  
19 level **806**, from second point **808** to third point **810**. In an alternative embodiment, first point  
20 **802** is about 10 Hz, crossover point **804** is about 100 Hz, predetermined level **806** is about 20 dB,  
21 second point **808** is about 600 Hz and third point **810** is about 2 KHz. In yet another alternative  
22 embodiment, crossover point **804** is about 60 Hz.

23 Figure 8 further depicts the response of the tailored bandpass amplifier, plotting  
24 amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In  
25 alternative embodiments, the response of sounds of interest **908** may be set at varying levels **910**.

26 Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography  
27 data. In the simultaneous display mode, the present invention provides for plotting  
28 electrocardiogram data and sonospectrography data as a function of intensity **1002** and time  
29 **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that  
30 may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be

1 visually correlated with a select part of the acoustic signal **1010** and differentially measured to  
2 within 23 millionths of a second. This allows an operator who may be less familiar with acoustic  
3 signatures to correlate the electrocardiogram signal, which may be well understood, with the  
4 acoustic signal.

5 Referring to Figures 10a, 10b, and 10c, the display methodology of the present invention  
6 is shown. The present invention provides a means to simultaneously display the signal of interest  
7 in a variety of different forms. In Figure 10a, the signal of interest of the present invention is  
8 presented as a simple time series, with acoustic amplitude **1102** on the vertical scale and time  
9 **1104** on the horizontal scale. In Figure 10b, the signal of interest of the present invention is  
10 presented as a time and frequency display, with relative amplitude **1106** of each slice of the  
11 frequency spectrum on the vertical scale and frequency spectrum **1108** on the horizontal display.  
12 In Figure 10c, the signal of interest of the present invention is presented with frequency **1110** on  
13 the vertical axis, time **1112** on the horizontal axis, and relative amplitude plotted in different  
14 color hues (not shown) and/or grey scale intensity.

15 Having thus described the basic concept of the apparatus of the invention, it will be  
16 readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be  
17 presented by way of example only, and is not limiting. Various alterations, improvements and  
18 modifications will occur and are intended to those skilled in the art, but are not expressly stated  
19 herein. For example, while cardiovascular monitoring is a key aspect of the invention, the  
20 techniques described herein are equally applicable to the monitoring of other body organs and  
21 regions of the body of both humans and animals and thus may also find utility in the veterinary  
22 sciences. These modifications, alterations and improvements are intended to be suggested  
23 hereby, and are within the spirit and scope of the invention.

## OPERATION

25 Figure 11 depicts the operation of the apparatus of the present invention with associated  
26 hardware and software. At step **1202**, start-up procedures are performed such as initialization,  
27 calibration, sensor selection, patient parameter input, and buffer clearing, among others. Upon  
28 completion of these start-up procedures steps **1204** and **1206** are initiated. At step **1204**, sensor  
29 **102** provides patient physiologic signals for signal processing. In an alternative embodiment,

1 sensor **102** can include electrocardiogram sensors and acoustic sensors. At step **1206** acoustic  
2 sensors are used to detect background or ambient noise.

3 Next, at step **1208**, the detected signals are passed to individual data acquisition modules  
4 which contain means for signal filtering, impedance matching, amplification, and buffering.  
5 These functions are performed by the components of the circuitry illustrated in Figs. 4-6.

6 At step **1210**, the signals from the ambient noise acoustic sensor acquired in step **1206**,  
7 are processed and subtracted from the signals from the desired sensor of step **1204** in a noise  
8 cancellation process to reduce the effect of ambient noise from the patient's environment.

9 At step **1212**, the signal undergoes additional signal conditioning and processing. The  
10 purpose of this conditioning step is to convert the analog signal to digital, provide adjustable  
11 decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing,  
12 averaging and peak holding. In an alternative embodiment the signal conditioning and  
13 processing of step **1212** is performed by a sound card which typically has the following  
14 capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16  
15 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion; and  
16 (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet another  
17 alternative embodiment the sound card used comprises a "Tahiti" multiple channel Sound Card  
18 manufactured by Turtle Beach. Step **1230** allows for the intermediate output and display of the  
19 desired signal following the signal conditioning and processing of step **1212**. The display is  
20 accomplished by selection of a desired display mode and subsequent display on the monitor **112**.  
21 The output of step **1212** is of a time series and is suitable for display selection as in Figure 10a.

22 At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier  
23 transformation. The output of step **1214** is of time and frequency and is suitable for display  
24 selection according to Figures 10b or 10c.

25 At step **1216**, time domain components of the data passes through a time domain  
26 correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency  
27 domain components of the data passes through a frequency domain correlator and feature  
28 extractor. In step **1220**, the outputs from the time domain correlator and feature extraction  
29 process of step **1216** and the frequency domain correlator and feature extractor of step **1218** are  
30 compared to a reference pattern and feature library, to determine whether the features contained

1 within the signal of interest match known disease modalities as recorded and maintained within  
2 the reference pattern and feature library.

3 At step **1222**, the outputs from the time domain correlator and feature extraction process  
4 of step **1216**, the frequency domain correlator and feature extractor process of step **1218** and the  
5 results from the reference pattern and feature library comparison of step **1220** are subjected to a  
6 recognition logic decision, where a determination is made as to whether a disease or adverse  
7 condition is indicated. At step **1224**, the new disease modality indicated in the recognition logic  
8 decision of step **1222** is then used to update the reference pattern and feature library of step **1220**.  
9 In step **1226** a desired display mode such as depicted in Figures 10a, 10b and 10c is chosen for  
10 subsequent display on the monitor **112**. At step **1228** the process is either terminated at step  
11 **1240** or begun anew at step **1202**.

12 The preceding descriptions of the operation of the present invention are merely  
13 illustrative. In various embodiments of the disclosed invention operational steps may be added,  
14 eliminated, performed in parallel or performed in a differing order.

15

16 METHOD

17

18 Sonospectrography can be used as a primary source of auscultatory information in a  
19 routine physical examination or in population screening. Sonospectrography can be used in  
20 cardiology and general medicine for the detection of functional and organic disorders of the heart  
21 such as congenital defects, valve function, diseases of the pericardium and myocardium and  
22 systemic and pulmonary hypertension. Sonospectrography can also be used as a traditional  
23 stethoscope to capture sounds generated by other organs, such as the lungs, trachea, larynx, liver  
24 and carotid arteries.

25 Elevated blood pressure has a number of causes. Regardless of the cause, however,  
26 recent testing at the Uniformed Services University of Health Sciences shows that there is a  
27 change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds that  
28 is directly correlated to change in blood pressure of the associated systemic or pulmonary  
29 circulatory system. This correlation was shown to be both measurable and repeatable in testing  
30 on animals having systemic and pulmonary circulatory systems comparable to the human system.

31 Elevated blood pressure increases back pressure at associated heart valves. This

Bpspec-PCT.WPD: December 3, 1997

1 increased back pressure results in more rapid closure of the heart valves and a resultant audible  
2 "snap" of the valve leaflets. The acoustic signature that is associated with those heart valve  
3 sounds has elevated frequency components as compared to the signature associated with heart  
4 valves operating under normal blood pressures. As the blood pressure increases, this frequency  
5 component also increases. It has been determined that this change in the frequency component  
6 is transitory and returns to normal when the blood pressure returns to normal.

7 Thus, where the sound emitted by the aortic semilunar valve is of an increased frequency,  
8 this is indicative of higher systemic blood pressure. Similarly, where the sound emitted by the  
9 pulmonary semilunar valve is of an increased frequency, this is indicative of higher pulmonic  
10 blood pressure. Through the use of the apparatus of the present invention, it is possible to detect  
11 and record sounds originating from the aortic and pulmonary semilunar valves.

12 In practice, a sensor assembly is placed in contact with the patient. One side of the sensor  
13 assembly contains an acoustic coupler that is placed in contact with the patient's skin at the  
14 traditional auscultation point for the valve of interest, while a second acoustic coupler on the  
15 opposite side faces away from the patient. This second acoustic coupler is designed to acquire  
16 background sounds in synchronism with the acoustic coupler in contact with the patient's skin to  
17 reject common mode signals reaching both couplers. While breathing normally the sounds of the  
18 aortic and/or pulmonary semilunar valves are acquired, preamplified and sent to a plurality of  
19 locations.

20 One analog signal is sent directly to an audio amplifier and high fidelity earphones. A  
21 second analog signal is sent through a gain control potentiometer to an analog to digital  
22 converter. The data is digitized and displayed in real time on a monitor. Visual feedback from  
23 the monitor allows a precise setting of the gain control by the physician for the optimum  
24 acquisition of data. In an alternative embodiment, an electronic strip chart is used in the precise  
25 setting of the gain control. The physician adjusts gain control to maximize the dynamic range of  
26 the captured signal.

27 In one embodiment, sounds are filtered normally. In an alternative embodiment, sounds  
28 are filtered to de-emphasize interfering responses prior to being sent to the earphones or the  
29 analog to digital converter. Data can be stored digitally, recalled for future analysis or  
30 transmitted to another location.

31 Referring to Figure 12, data from recent in-vivo testing on animal subjects at the

1 Uniformed Services University of Health Sciences is shown. The subject had a pressure catheter  
2 emplaced to provide actual pressure readings, and the present invention detected, and processed  
3 the acoustic signature data from the second heart sounds. Figure 12 plots the relationship  
4 between second heart sound A2 **1302**, and blood pressure **1304**. As shown, where there is a rise  
5 in the frequency of second heart sound **1302**, there is a corresponding rise in systolic pressure  
6 **1306**, mean pressure **1308** and diastolic pressure **1310**.

7 The subject whose pressure/frequency relationship is depicted in Figure 12, had a resting  
8 systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg, and a  
9 predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was thus about  
10 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased, the associated  
11 frequency components of the second heart sound correspondingly increased. Systolic pressure  
12 **1306** of the subject reached about 165 mm Hg, diastolic pressure **1310** reached about 85 mm Hg,  
13 and frequency of second heart sound **1302** reached 36. Mean pressure **1308** reached about 115  
14 mm Hg. The slope of this mean pressure/frequency curve is approximately 2 mm Hg per Hz.  
15 This pressure/frequency correlation was demonstrated in each animal subject tested.

16 Across a population, measurement of the sound frequency associated with the closure of  
17 the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and  
18 pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected  
19 from population samples, the present invention will allow an estimate of the mean systemic and  
20 pulmonary pressure with a passive and non-invasive acoustic measurement of the acoustic  
21 signature of the semilunar valve closure. As an example, if the mean pressure data curve **1307** in  
22 Figure 12 presented an accumulated average from the population, then measurement of a  
23 pulmonary semilunar valve closure sound frequency of 36 Hz **1309** would provide an estimate  
24 that the mean pulmonic pressure was 115 mm Hg **1311**. In an otherwise asymptomatic patient,  
25 this might provide sufficient clinical justification for use of an invasive blood pressure catheter,  
26 with the attendant risk and cost, to confirm the pulmonic pressure.

27 Although the method of the present invention has been described in detail for purpose of  
28 illustration, it is understood that such detail is solely for that purpose, and variations can be made  
29 therein by those skilled in the art without departing from the spirit and scope of the invention.  
30 The apparatus, operation and method of the present invention is defined by the following claims.

**WHAT IS CLAIMED IS:**

1           1. An apparatus for monitoring blood pressure comprising:  
2           a means for detecting audio signals;  
3           a means for signal processing connected to the signal detecting means;  
4           a means for signal storage connected to the signal processing means; and  
5           a means for monitoring, connected to the signal processing means.

6           2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
7           audio signal detecting means is a sensor assembly.

8           3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
9           audio signal detecting means is a plurality of sensor assemblies.

10           4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the  
11           sensor assembly comprises:

12           a housing having a front and a back;  
13           an electronic module connected to the housing;  
14           a shock dampener connected to the front of the housing;  
15           a means for mounting connected to the housing;  
16           a transducer connected to the mounting means;  
17           an acoustic coupling connected to the transducer; and  
18           a cover connected to the back of the housing.

19           5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
20           housing further comprises a sound deadening material.

21           6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the  
22           housing further comprises nickel plated aluminum.

23           7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
24           housing further comprises:

25           a rim having an inside and an outside, located on the periphery of the front of the  
26           housing;  
27           a first indentation having an inside and an outside, that runs parallel and adjacent to the  
28           inside of the rim;  
29           a second indentation that runs parallel and adjacent to the inside of the first indentation;

1 and

2 a bore that is approximately centrally located within the second indentation.

3 8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the  
4 electronic module nests within the bore.

5 9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
6 shock dampener is an "O" ring.

7 10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
8 mounting means is a plastic mounting ring.

9 11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
10 transducer is a piezoelement.

11 12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the  
12 acoustic coupling is a parametric acoustic transconductor.

13 13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein the  
14 parametric acoustic transconductor comprises latex foam.

15 14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
16 signal processing means is a computer with a central processing unit.

17 15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein the  
18 computer with a central processing unit is an IBM compatible personal computer.

19 16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
20 means for signal storage further comprises an array of disks.

21 17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
22 means for signal storage further comprises an internal hard disk drive.

23 18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
24 means for signal storage further comprises an internal hard disk drive.

25 19. An apparatus for monitoring blood pressure as claimed in claim 1, further  
26 comprising:

27 a means for hard copy reproduction connected to the signal processing means.

28 20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein the  
29 means for hard copy reproduction further comprises a printer.

30 21. An apparatus for monitoring blood pressure as claimed in claim 1, further  
31 comprising:

1 a means for remote connection connected to the signal processing means.

2 22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein the  
3 means for remote connection further comprises a modem.

4 23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
5 means for monitoring further comprises a high resolution EGA color display monitor.

6 24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the  
7 means for monitoring further comprises a high resolution VGA color display monitor.

8 25. An apparatus for monitoring blood pressure as claimed in claim 1, further  
9 comprising:

10 a means for data acquisition connected to the signal detection means and the signal  
11 processing means.

12 26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein the  
13 means for data acquisition comprises an amplifier.

14 27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein the  
15 amplifier comprises a tailored bandpass amplifier.

16 28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein the  
17 tailored bandpass amplifier comprises a low frequency response from a predetermined first point  
18 to a predetermined second point, and a higher frequency response of a predetermined level, from  
19 the predetermined second point to a predetermined third point.

20 29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the  
21 predetermined level is about 20 dB.

22 30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the  
23 predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz and  
24 the predetermined third point is about 600 Hz.

25 31. An apparatus for monitoring blood pressure as claimed in claim 28, where in the  
26 predetermined second point is about 60 Hz.

27 32. A method of determining blood pressure comprising:

28 performing initialization procedures;

29 acquiring physiologic signals;

30 acquiring background signals;

31 subtracting background signals from physiologic signals creating physiologic data;

1 processing physiologic data forming a time domain output and a frequency domain data  
2 output;

3 comparing the time domain output and the frequency domain output with a reference  
4 pattern and feature library; and

5 determining if a disease modality is indicated.

6 33. A method of determining blood pressure as claimed in claim 32, wherein  
7 performing initialization further comprises:

8 initializing system;

9 calibrating system;

10 selecting sensors;

11 inputting patient parameters; and

12 clearing buffers.

13 34. A method of determining blood pressure as claimed in claim 32, wherein  
14 acquiring physiologic signals comprises acquiring acoustic signals.

15 35. A method of determining blood pressure as claimed in claim 32, wherein  
16 acquiring physiologic signals comprises acquiring electric signals.

17 36. A method of determining blood pressure as claimed in claim 32, wherein the  
18 physiologic signals are in an analog form, further comprising:

19 converting the physiologic signals from the analog form to a digital form.

20 37. A method of determining blood pressure as claimed in claim 32, wherein the  
21 background signals are in an analog form, further comprising the step:

22 converting the background signals from the analog form to a digital form.

23 38. A method of determining blood pressure as claimed in claim 32, wherein  
24 processing further comprises:

25 applying signal conditioning and time domain averaging to the physiologic data forming  
26 conditioned and averaged data;

27 formatting the conditioned and averaged data in an array creating formatted data;

28 aligning and normalizing formatted data, creating aligned and formalized data;

29 normalizing and integrating the aligned and formalized data, creating normalized and  
30 integrated data, wherein said normalized and integrated data has time domain components and  
31 frequency domain components;

1                   passing the time domain components of the normalized and integrated data through a  
2 time domain correlator and feature extraction process; and

3                   passing the frequency domain components of the normalized and integrated data through  
4 a frequency domain correlator and feature extractor, creating the time domain output and the  
5 frequency domain output.

6           39.    A method of determining blood pressure as claimed in claim 38, further  
7 comprising:

8                   displaying the formatted data on a monitor.

9           40.    A method of determining blood pressure as claimed in claim 38, further  
10 comprising:

11                   displaying the aligned and normalized data on a monitor.

12           41.    A method of determining blood pressure as claimed in claim 38, further  
13 comprising:

14                   displaying the normalized and integrated data on a monitor.

15           42.    A method of determining blood pressure as claimed in claim 32, further  
16 comprising:

17                   updating the reference pattern and feature library.

18           43.    A method of determining systemic blood pressure using sonospectrography  
19 analysis comprising:

20                   monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein the  
21 sound is detected using a sensor assembly, to monitor physiologic signals, the sensor assembly  
22 comprising:

23                   a housing having a front and a back;

24                   an electronic module connected to the housing;

25                   a shock dampener connected to the front of the housing;

26                   a means for mounting connected to the housing;

27                   an acoustic coupler connected to the mounting means;

28                   a transducer connected to the acoustic coupler; and

29                   a cover connected to the back of the housing;

30                   processing the physiologic signals, the processing comprising:

31                   applying signal conditioning and time domain averaging to the physiologic signals

1 to form conditioned and averaged data;  
2 formatting the conditioned and averaged data in an array to create formatted data;  
3 aligning and normalizing formatted data, to create aligned and formalized data;  
4 normalizing and integrating the aligned and formalized data, to create normalized  
5 and integrated data that has time domain components and frequency domain  
6 components;  
7 passing the time domain components of the normalized and integrated data  
8 through a time domain correlator and feature extraction process;  
9 passing the frequency domain components of the normalized and integrated data  
10 through a frequency domain correlator and feature extractor, to create a time  
11 domain output and a frequency domain output;  
12 comparing time domain output and the frequency domain output with a reference pattern  
13 and feature library; and  
14 determining if a disease modality is indicated.

15 44. A method of determining systemic blood pressure using sonospectrography  
16 analysis as claimed in claim 43, further comprising:  
17 acquiring background signals; and  
18 subtracting background signals from physiologic signals.

19 45. A sensor assembly for detecting physiological sounds comprising:  
20 a housing having a front and a back;  
21 an electronic module connected to the housing;  
22 a shock dampener connected to the front of the housing;  
23 a means for mounting connected to the shock dampener;  
24 an acoustic coupler connected to the mounting means;  
25 a transducer connected to the acoustic coupler; and  
26 a cover connected to the back of the housing.

27 46. A sensor assembly as claimed in claim 45, wherein the housing further comprises  
28 a sound deadening material.

29 47. A sensor assembly as claimed in claim 46, wherein the housing further comprises  
30 nickel plated aluminum.

31 48. A sensor assembly as claimed in claim 45, wherein the housing further comprises:

1           a rim having an inside and an outside, that is located on the periphery of the front of the  
2 housing;

3           a first indentation having an inside and an outside, that runs parallel and adjacent to the  
4 inside of the rim;

5           a second indentation that runs parallel and adjacent to the inside of the first indentation;  
6 and

7           a bore, that is approximately centrally located within the second indentation.

8       49.    A sensor assembly as claimed in claim 48, wherein the electronic module nests  
9 within the bore.

10      50.    A sensor assembly as claimed in claim 45, wherein the shock dampener is an "O"  
11 ring.

12      51.    A sensor assembly as claimed in claim 45, wherein the mounting means is a  
13 plastic mounting ring.

14      52.    A sensor assembly as claimed in claim 45, wherein the transducer is a  
15 piezoelement.

16      53.    A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a  
17 parametric acoustic transconductor.

18      54.    A sensor assembly as claimed in claim 53, wherein the parametric acoustic  
19 transconductor comprises latex foam.

20      55.    A sensor assembly for detecting physiological sounds comprising:

21           a housing, having a front, a back, and an interior;

22           an electronic module that nests in the interior of the housing;

23           a first shock dampener connected to the front of the housing;

24           a first mounting means connected to the first shock dampener;

25           a transducer connected to the first mounting means;

26           a first acoustic coupling connected to the transducer;

27           a second shock dampener connected to the back of the housing;

28           a second mounting means connected to the second shock dampener;

29           a second transducer connected to the second mounting means; and

30           a second acoustic coupling connected to the second transducer.

31      56.    A sensor assembly as claimed in claim 55, wherein the housing further comprises

1 a sound deadening material.

2 57. A sensor assembly as claimed in claim 56, wherein the housing further comprises  
3 nickel plated aluminum.

4 58. A sensor assembly as claimed in claim 55, wherein the housing further comprises:  
5 a first rim having an inside and an outside, that is located on the periphery of the front of  
6 the housing;

7 a first indentation having an inside and an outside, that runs parallel and adjacent to the  
8 inside of the first rim;

9 a second indentation that runs parallel and adjacent to the inside of the first indentation;  
10 a bore, that is approximately centrally located within the second indentation;

11 a second rim having an inside and an outside, that is located on the periphery of the back  
12 of the housing;

13 a third indentation having an inside and an outside, that runs parallel and adjacent to the  
14 inside of the second rim; and

15 a fourth indentation, that runs parallel and adjacent to the inside of the third indentation.

16 59. A sensor assembly as claimed in claim 58, wherein the electronic module nests  
17 within the bore.

18 60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is an  
19 "O" ring and the second shock dampener is an "O" ring.

20 61. A sensor assembly as claimed in claim 58, wherein the first mounting means is a  
21 plastic mounting ring and the second mounting means is a plastic mounting ring.

22 62. A sensor assembly as claimed in claim 58, wherein the first transducer is a  
23 piezoelement and the second transducer is a piezoelement.

24 63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling is a  
25 parametric acoustic transconductor and the second acoustic coupling is a parametric acoustic  
26 transconductor.

27 64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic  
28 transconductor comprises latex foam.

29 65. An apparatus for determining blood pressure comprising:  
30 an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic  
31 transmission coupling between skin and a piezoelectric transducer.

1       66. An apparatus for determining blood pressure as claimed in claim 65, wherein the  
2 acoustic coupling is a parametric acoustic transconductor.

3       67. An apparatus for determining blood pressure as claimed in claim 65, wherein the  
4 acoustic coupling has a high conduction coefficient.

5       68. An apparatus for determining blood pressure as claimed in claim 65 wherein the  
6 acoustic coupling comprises latex foam.

7       69. An apparatus for monitoring blood pressure comprising:

8           an acoustic coupling;

9           a transducer connected to the acoustic coupling;

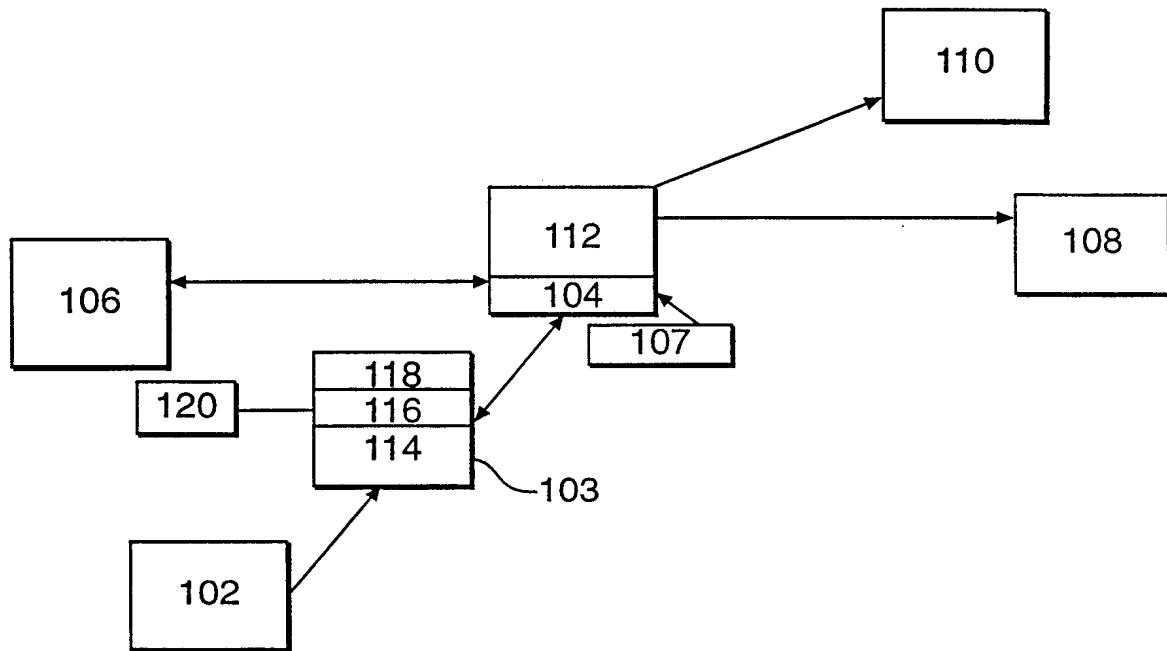
10          an electronic module connected to the transducer;

11          a data acquisition module connected to the electronic module; and

12          a data cable connected to the electronic module and the data acquisition module.

13       70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein the  
14 data cable is a twisted shielded pair.

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***FIG. 1***

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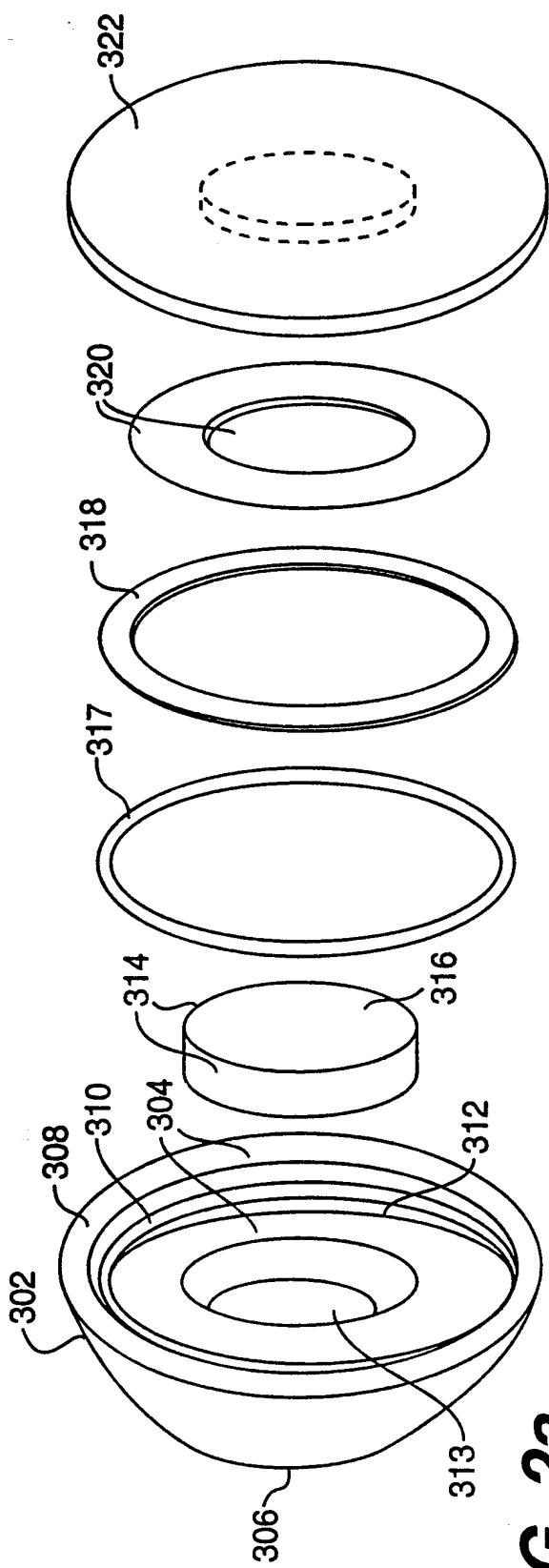


FIG. 2a

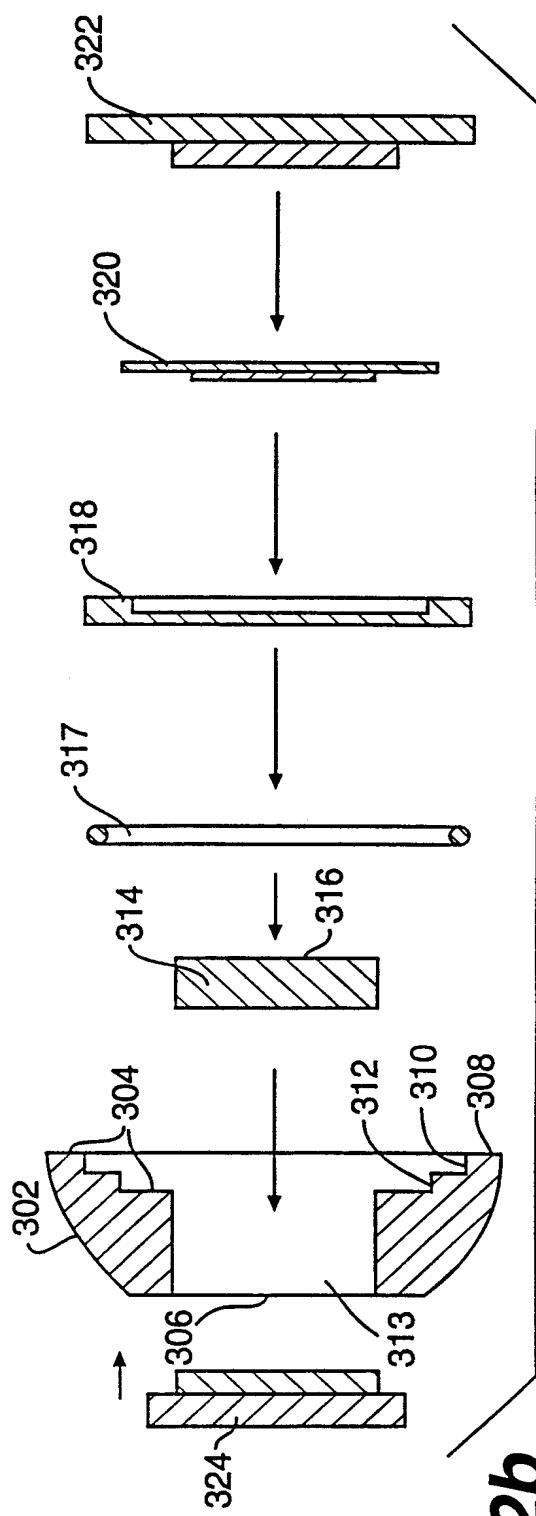
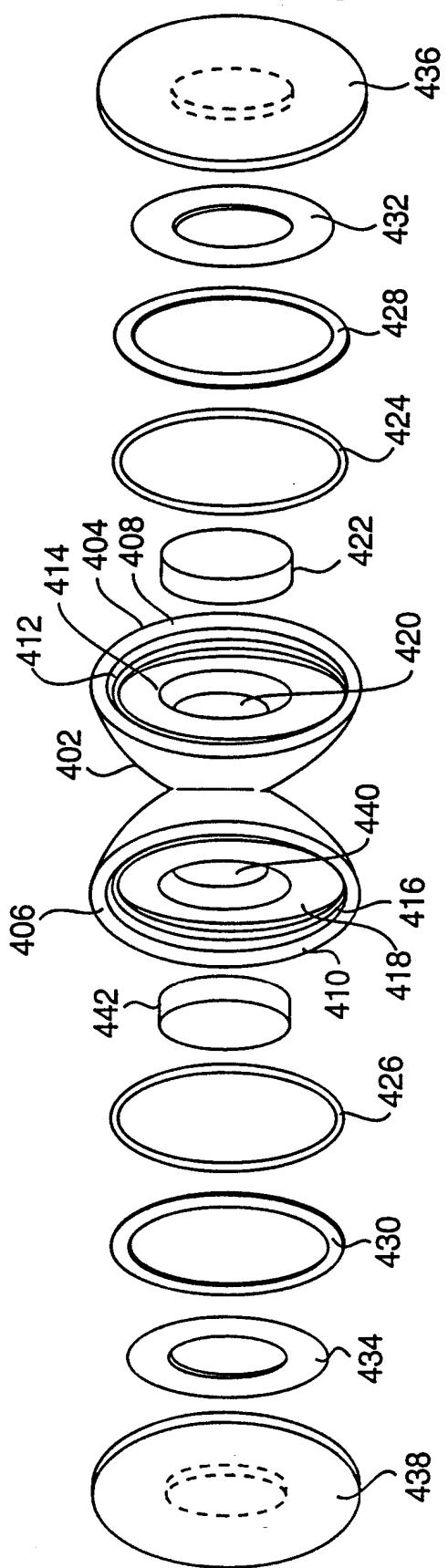
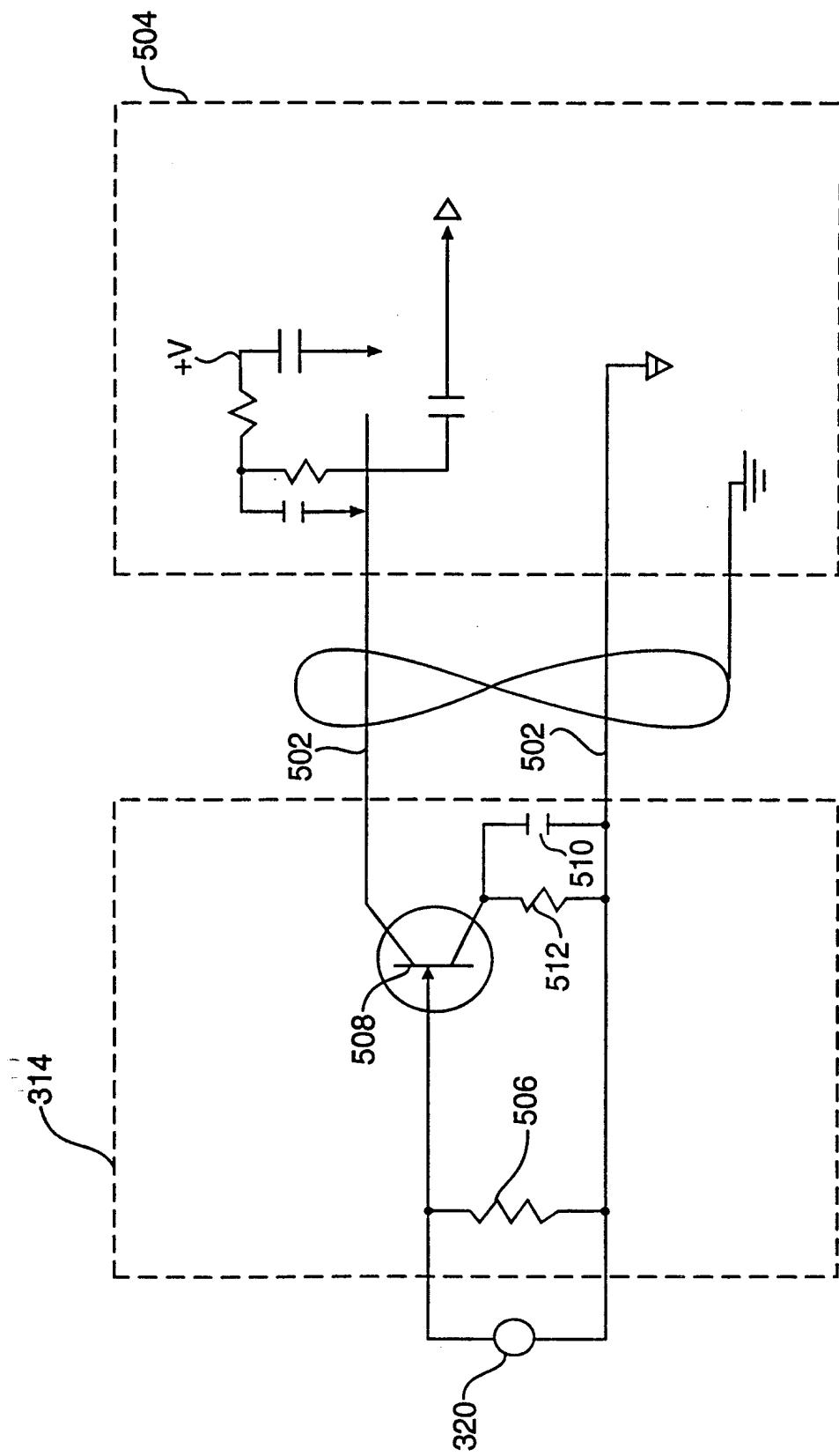


FIG. 2b

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**FIG. 3**



**FIG. 4**

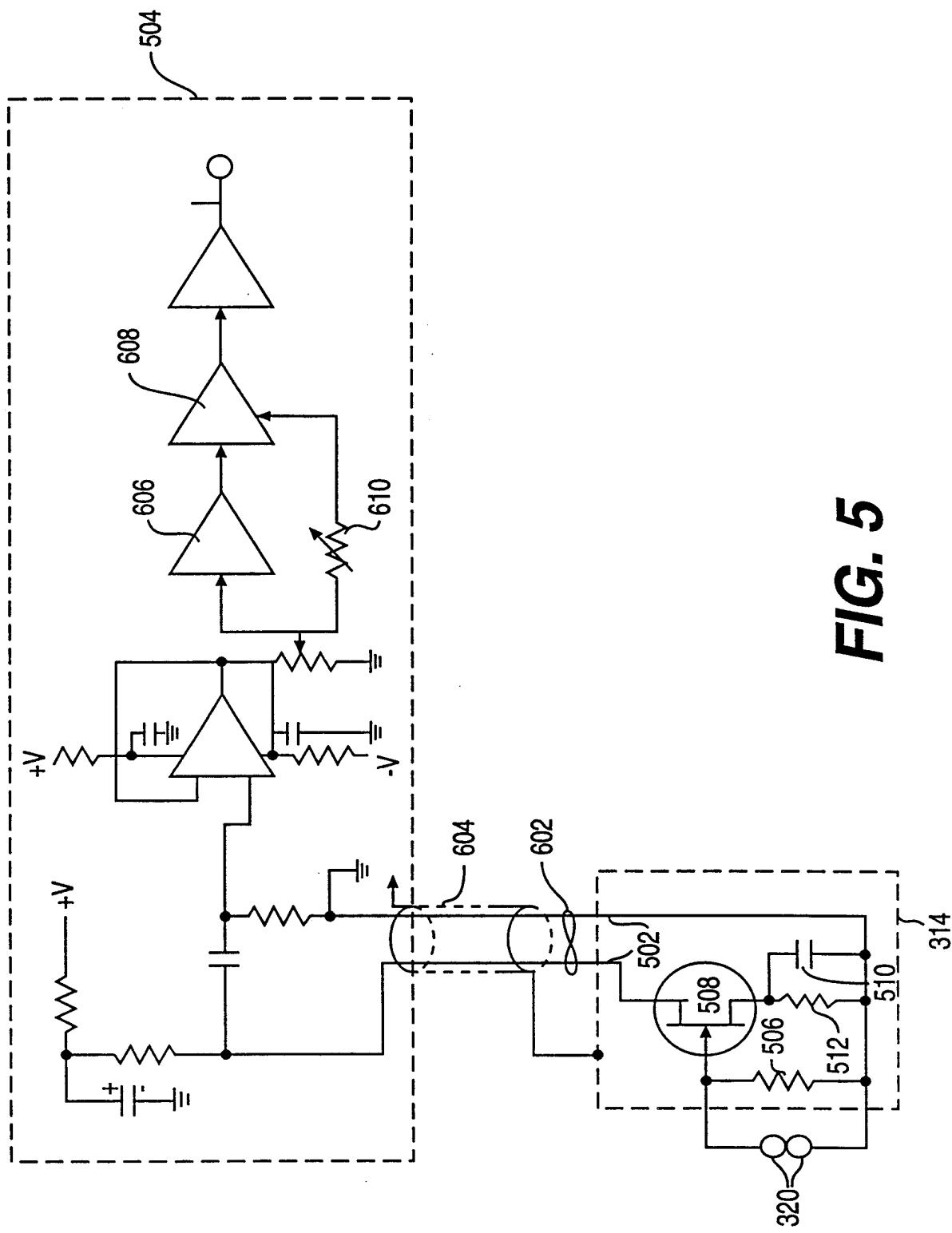


FIG. 5

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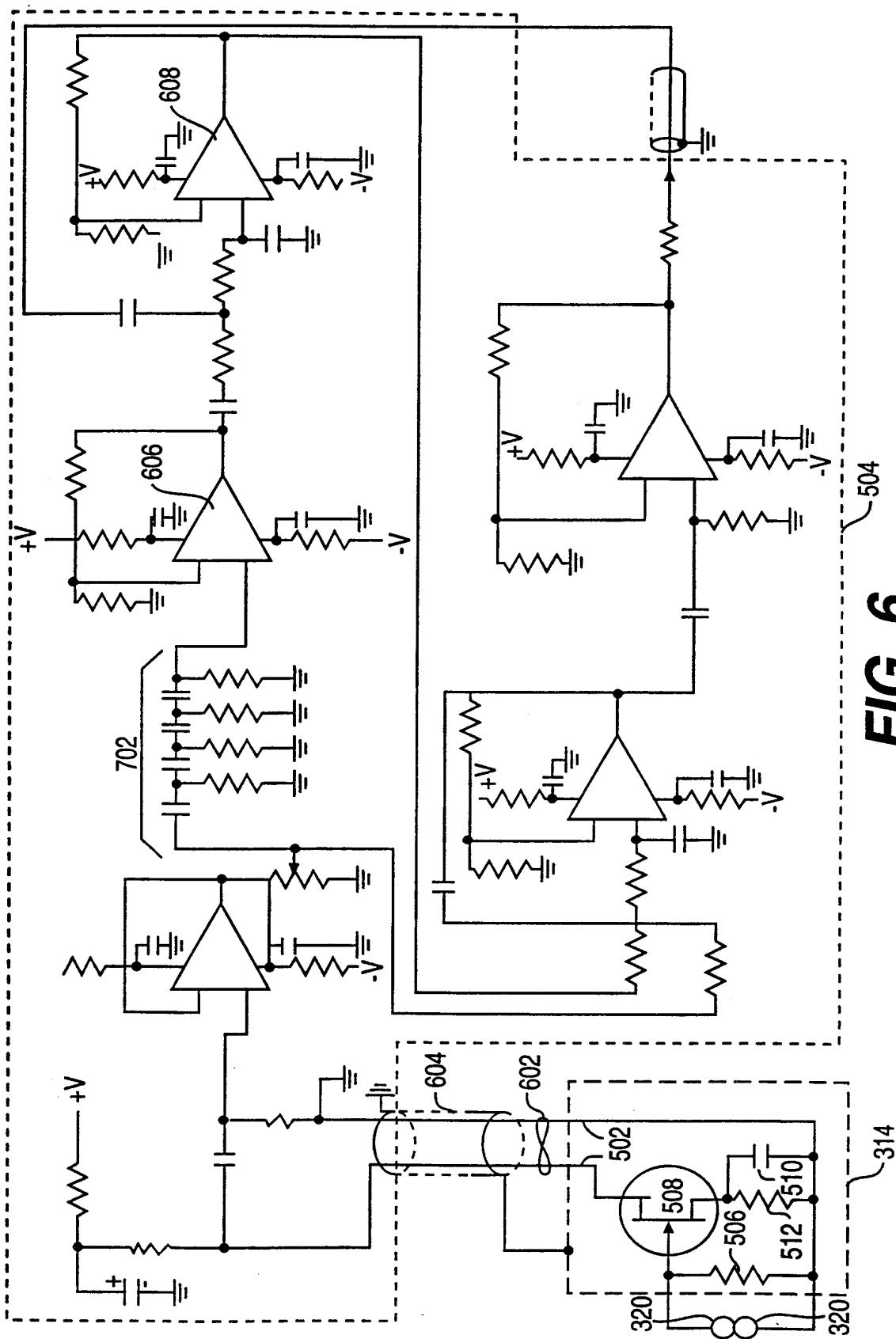


FIG. 6

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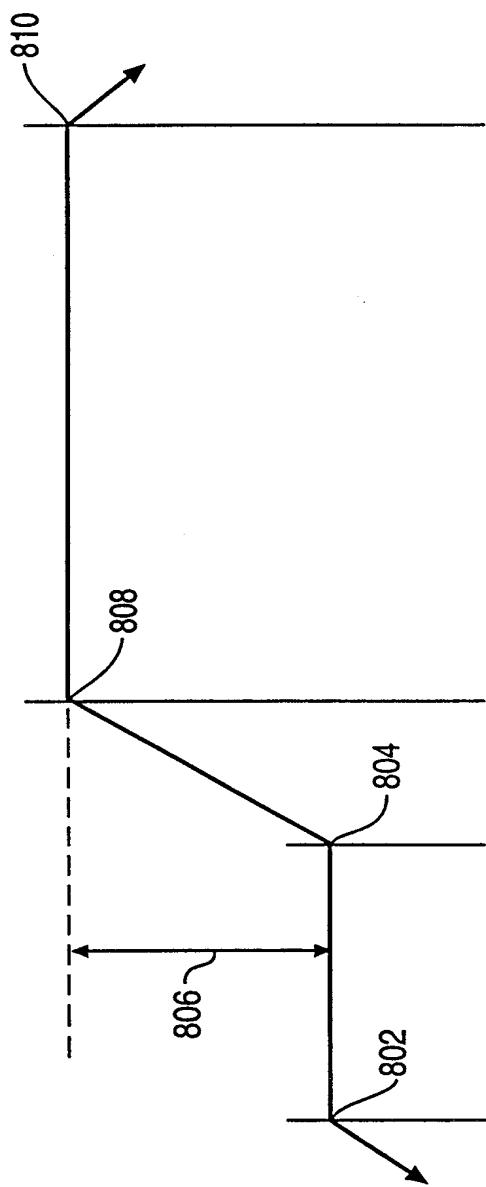


FIG. 7

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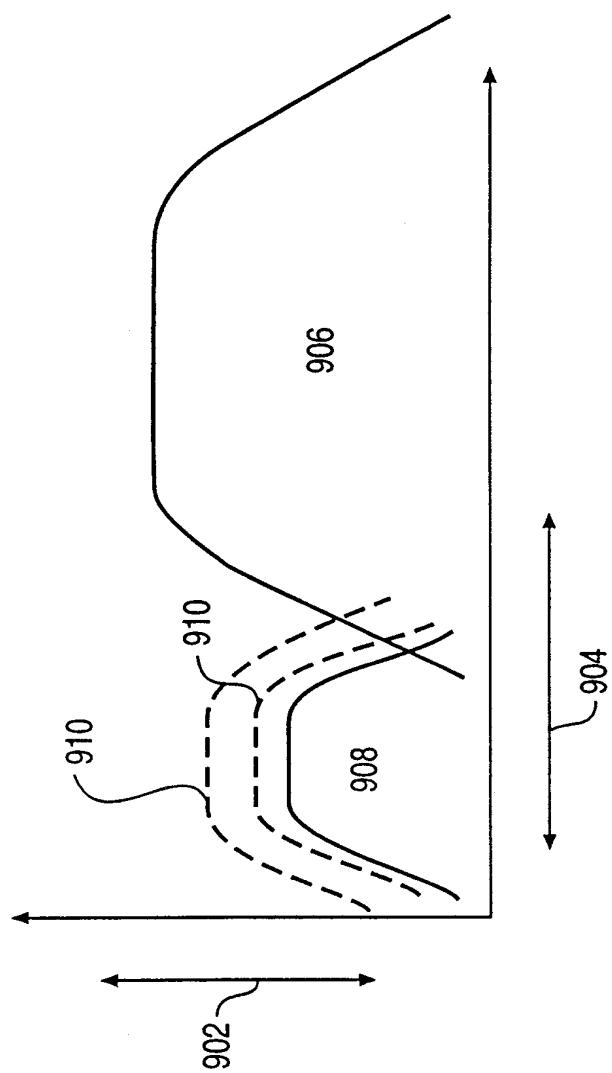


FIG. 8

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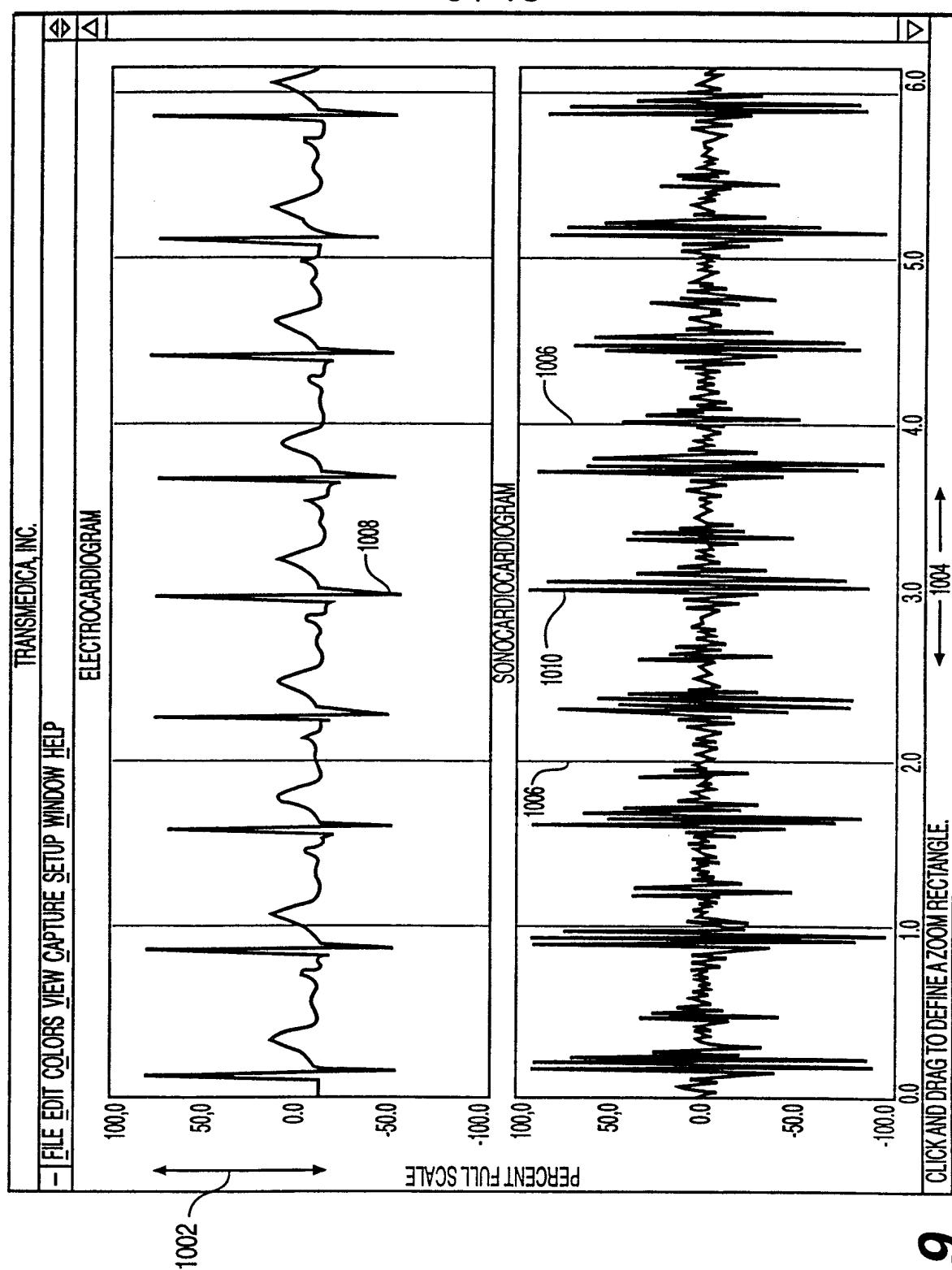
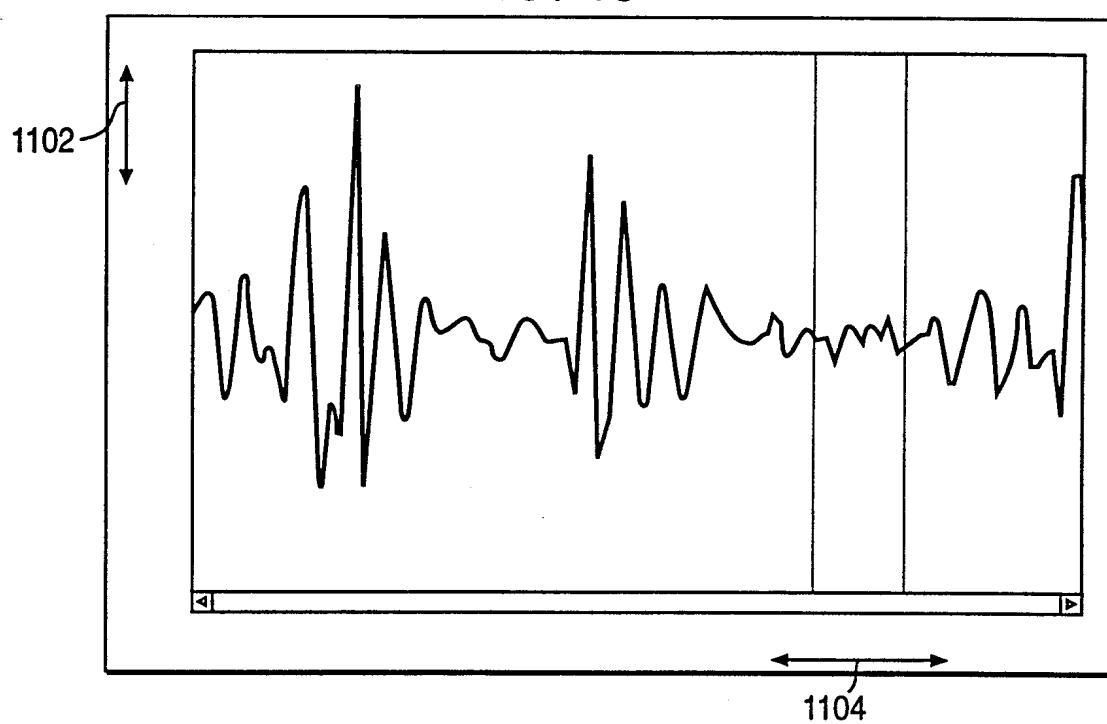
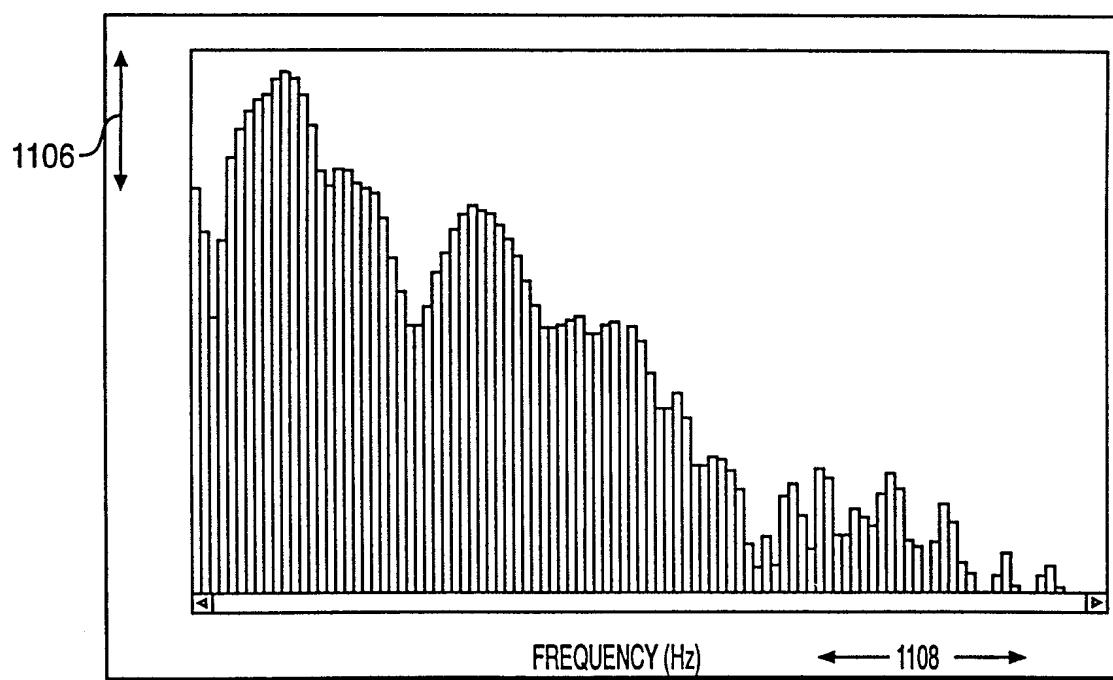
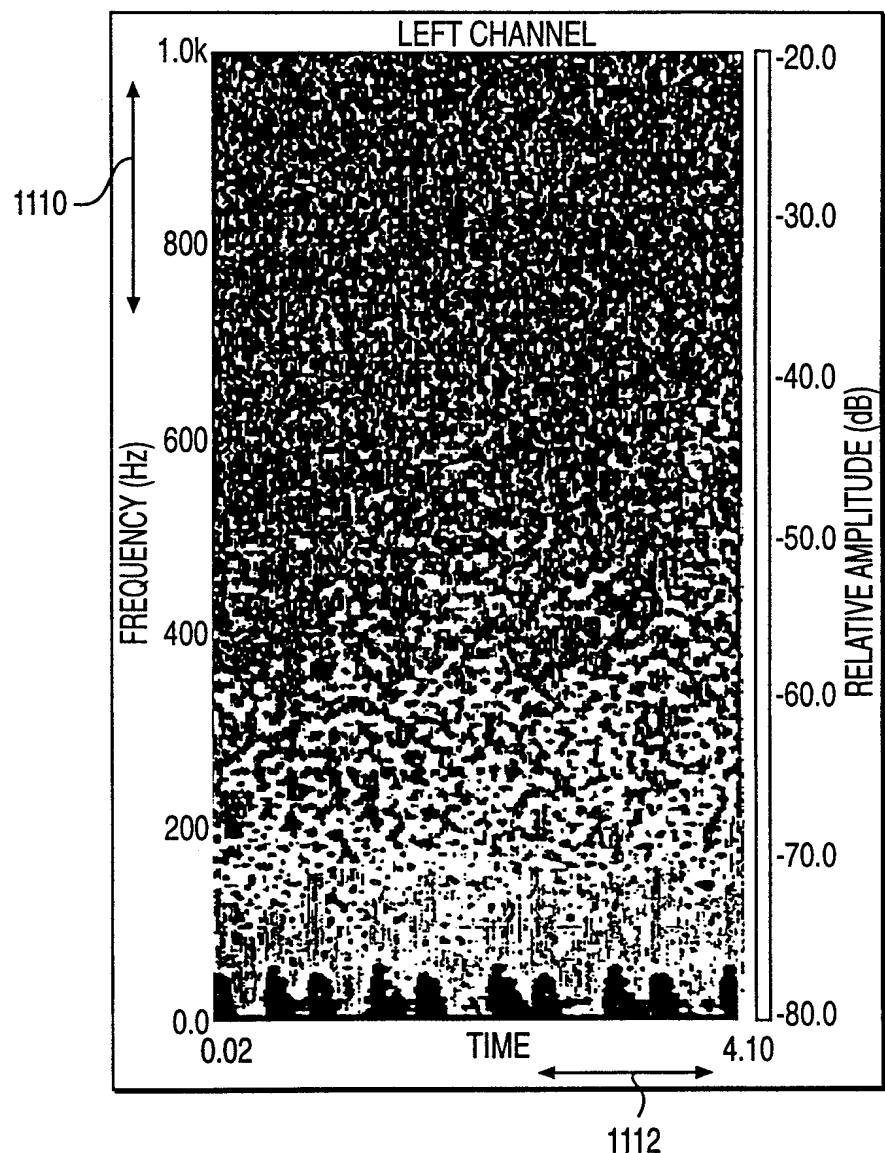


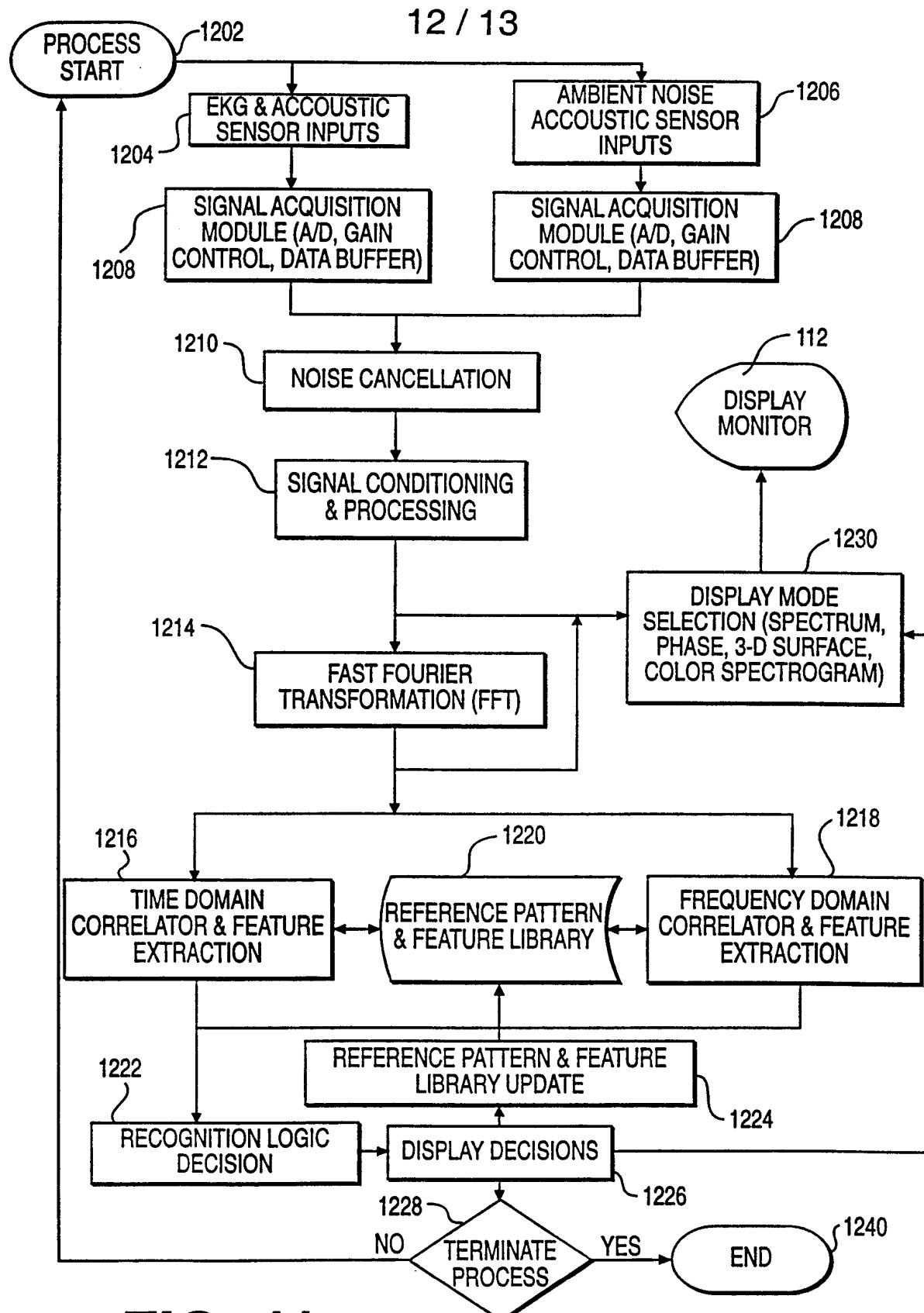
FIG. 9

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**FIG. 10a****FIG. 10b**

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**FIG. 10c**

**FIG. 11**

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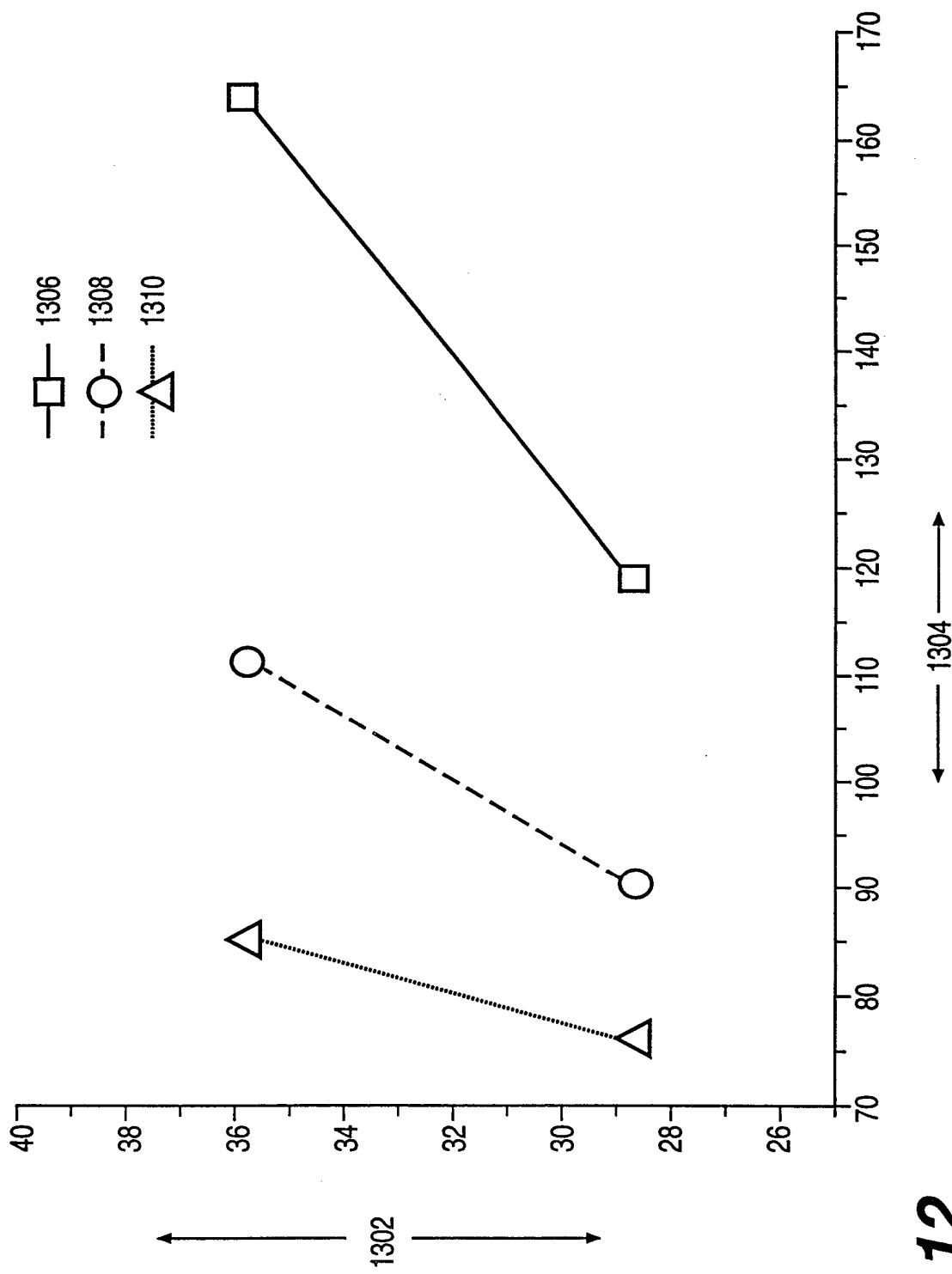


FIG. 12

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 97/21917

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B7/04

According to International Patent Classification(IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPAARI) 10 December 1980	1-4, 7, 9-11, 14, 25, 26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65, 69
A	see page 3, line 4 - line 37	6, 47, 55
A	see page 7, line 11 - page 9, line 18 see page 12, line 24 - page 17, line 17 ---	57, 58 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

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1

Date of the actual completion of the international search

Date of mailing of the international search report

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Rieb, K.D.

**INTERNATIONAL SEARCH REPORT**

Inte onal Application No	
PCT/US 97/21917	

**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 467 775 A (T.F. CALLAHAN ET AL.) 21 November 1995	1-3, 5, 10, 14, 21, 25-28, 44-46, 48, 51, 55, 56, 69
A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43, 58
A	see column 8, line 5 - line 44	65, 67
	see column 11, line 56 - column 12, line 55	---
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A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36, 39
A	see column 9, line 9 - column 10, line 45	40, 43-46
A	see column 10, line 66 - column 11, line 24	55, 56, 65, 67, 69
	see column 13, line 64 - column 15, line 31	---
A	US 5 025 809 A (K.H. JOHNSON ET AL.) 25 June 1991	1, 14, 25, 32, 34-36
A	see column 6, line 19 - column 9, line 20	38-43
A	US 5 205 295 A (B. DEL MAR ET AL.) 27 April 1993	1, 14, 16-20, 25, 35
A	see column 9, line 46 - column 11, line 44	36, 38-42
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Information on patent family members

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			PCT/US 97/21917	
Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
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